ortho·cell
advancing tissue repair & regeneration

Company Update Presentation

Perth, Australia 21 November 2017: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to release an updated company presentation. The presentation outlines Orthocell's compelling investment highlights and development and commercialisation strategy and follows the recent receipt of European regulatory approval (CE Mark) for CelGro® for a range of dental bone and soft tissue regeneration procedures.

Investment Highlights:

- **Significant upside potential** driven by Orthocell's product portfolio and underpinned by recent transactions in the sector
- Orthocell's key products **address markets worth more than US$10 billion p.a.**
- **Recently received marketing authorisation of CelGro®** collagen scaffold medical device in the European Union (CE Mark) for dental bone and soft tissue reconstructive applications
- CelGro® regulatory **approval acts to validate the entire technology platform** and can be leveraged for additional indications
- **Collaboration with Johnson & Johnson** to advance world leading cell therapy for tendon repair
- Substantial clinical data and strong partner interest from large pharmaceutical companies provides **de-risked investment proposition**
- **TGA licensed and GMP certified manufacturing capabilities** underpin competitive advantage and can be scaled to market demand
- Experienced founders and management team with **successful track record** developing, commercialising and monetising cell therapy products

Board and Management Commentary:

"We are pleased with the significant progress we have made this year. Orthocell has achieved a number of key milestones and we are now rapidly approaching exciting value inflection points. This includes signing research collaboration agreement with DePuy Synthes Products, part of the Johnson & Johnson Medical Devices Companies for Ortho-ATI®, our stem cell approach for the regeneration of damaged tendon and ligaments. To compliment this, Orthocell's CelGro® received marketing authorisation (CE Mark) in the EU. The CE Mark allows us to accelerate the commercial rollout of CelGro® in the lucrative dental bone and soft tissue regeneration market and positions Orthocell at the forefront of a large and growing market opportunity. Orthocell is in the midst of an exciting stage of growth and are well positioned to accelerate commercialisation of its regenerative medicine technologies." said Managing Director of Orthocell, Paul Anderson

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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 tendon, cartilage and 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. The Company's other major product is Celgro®, a collagen medical device which facilitates tissue repair and healing in a variety of orthopaedic, reconstructive and surgical applications and is being readied for first regulatory approvals.

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**

Investor Presentation

Advancing tissue repair and regeneration

November 2017

Paul Anderson Managing Director

ortho·cell

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- Substantial clinical data and strong partner interest from large pharmaceutical companies provides **de-risked investment proposition**
- **TGA[1] licensed and GMP[1] certified manufacturing capabilities** underpin competitive advantage and can be scaled to market demand
- Experienced founders and management team with **successful track record** developing, commercialising and monetising cell therapy products

1. TGA: Therapeutic Goods Administration; GMP: Good Manufacturing Practices

Corporate overview

A diversified health care exposure, delivering breakthrough products in regenerative medicine, with treatments along the soft tissue therapy continuum spectrum

Share price performance

Trading information

Share price (17-Nov-17)	A$0.385
Shares on issue[1]	101.5m
Market capitalisation	**A$39.1m**
Cash (as at 30-Sep-17)	A$5.3m[2]
Debt (as at 30-Sep-17)	-
Enterprise value	**A$33.7m**

Top shareholders (as at Aug-17)

Stone Ridge Ventures – *Associated with non-executive director*	10.0%
Ming Hao Zheng – *CSO and founder*	6.9%
Paul Anderson – *Managing director*	6.9%
Qi Xiao Zhou – *Non-executive director*	5.9%
Australian Super – *Superannuation and pension fund*	5.6%
Jia Xun Xu – *Former director*	5.1%

1. Excludes 12.1m unquoted warrants with exercise price $0.58, expiry 19-Nov-2020 and 8.8m unquoted options with exercise prices ranging from $0.50-$0.65 and expiry dates between Nov-2017 and Jun-2020
2. Cash figure based on A$3.0m held at 30-Sep-17 and A$2.3m R&D tax incentive cash refund received in Oct-17

Historical development timeline

Orthocell is currently at a major inflection point as it accelerates the commercialisation of its key products that have more than 10 years of clinical development and product validation

Pre 2015

- ✓ Acquisition of key intellectual property
- ✓ Construction and accreditation of GMP laboratory facility
- ✓ Relevant ethics approvals received
- ✓ Granted TGA licence for manufacturing
- ✓ Patent granted for ATI manufacturing and Ortho-ATI®
- ✓ First royalties generated
- ✓ Listed on the ASX in Aug 2014

Key clinical milestones achieved

2015

Mar: Approval received for CelGro® dental study

Apr: Long term study showing Ortho-ATI® effective for tennis elbow published in leading publication

Jul: Cell factory for bone and cartilage regeneration validated in leading publication

Jul: Grant received for lab grown tendon project

Oct: Workers compensation study proves Ortho-ATI® repairs tendon injuries

Nov: Early successful results for CelGro® dental study

Dec: Approval received for CelGro® tendon study

2016

May: Approval for hip cartilage regeneration study using CelGro®

Jun: Early successful results for CelGro® tendon study

Jul: Approval received for Ortho-ATI® (vs. Surgery study)

Oct: Approval received for CelGro® nerve regeneration study

2017

Jan: Signed research collaboration agreement with DePuy Synthes (J&J)

Feb: Commenced US FDA application process for CelGro® and early successful results for CelGro® nerve regeneration

May: Ethics approval received for Depuy Synthes (J&J) Ortho-ATI® Tendon Study

May: Ortho-ACI® included on the Australian Register of Therapeutic Goods

Oct: Surgical Specialities appointed as exclusive distributor

Nov: CelGro® receives marketing authorisation in the European Union (CE Mark)

Since listing, Orthocell has received numerous patents for key products (Ortho-ATI®, CelGro® and 'Cell Factory') across key geographic markets (US, Canada, Europe, Australia, NZ, Singapore, China, HK)

Clinical development, product and technology validation and manufacturing optimisation → **Execution of commercialisation strategy**

Founders story

Founders have extensive commercial and scientific experience in regenerative medicine, having previously demonstrated success in developing, commercialising and exiting cell therapy products with Verigen Australia

Paul Anderson
Managing Director

- **20+ years' experience** within the medical device and cellular therapy fields, with intimate knowledge of the regenerative medicine space
- 15+ years' experience in Board and CEO roles, including as **the former Managing Director and Executive Director of Verigen Australia, prior to its sale to Genzyme for US$50m in 2005**
- Responsible for the **introduction of first-generation autologous chondrocyte implantation (ACI) treatments, establishing Verigen's manufacturing capabilities** and key business development
- Key expertise in the development of emerging medical technology business, including extensive experience in:
  - **Establishing GMP manufacturing facilities** for cell therapies
  - **Commercial scaling activities** for cell therapies and biological medical devices, including sales and marketing and business development activities
  - **Regulatory pathways** of key global markets, including USA, Europe and Asia

Professor Ming-Hao Zheng
Chief Scientific Officer

- Pathologist and i**nventor of the Orthocell's technologies** (Ortho-ATI® and CelGro®) bringing a strong track record of innovation with 15+ years of experience
  - Current Director of Research in the Department of Orthopaedic Surgery, School of Surgery and Pathology, University of Western Australia
- **Proven ability to transform research into clinical practice** – research focused on finding novel approaches in the treatment for osteoporosis, osteoarthritis and tendon injuries using cutting edge cellular and molecular biology techniques
  - Has **published over 150 papers and holds seven patents** in the field of Orthopaedics
- **Former CSO of Verigen Australia** and led the first TGA approval of the ACI therapy
  - Pivotal in establishing Verigen Australia's clinical GMP laboratory

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

Orthocell strategy

Comprehensive strategy in place across key products to optimise shareholder value

Product development and validation

Optimised manufacturing

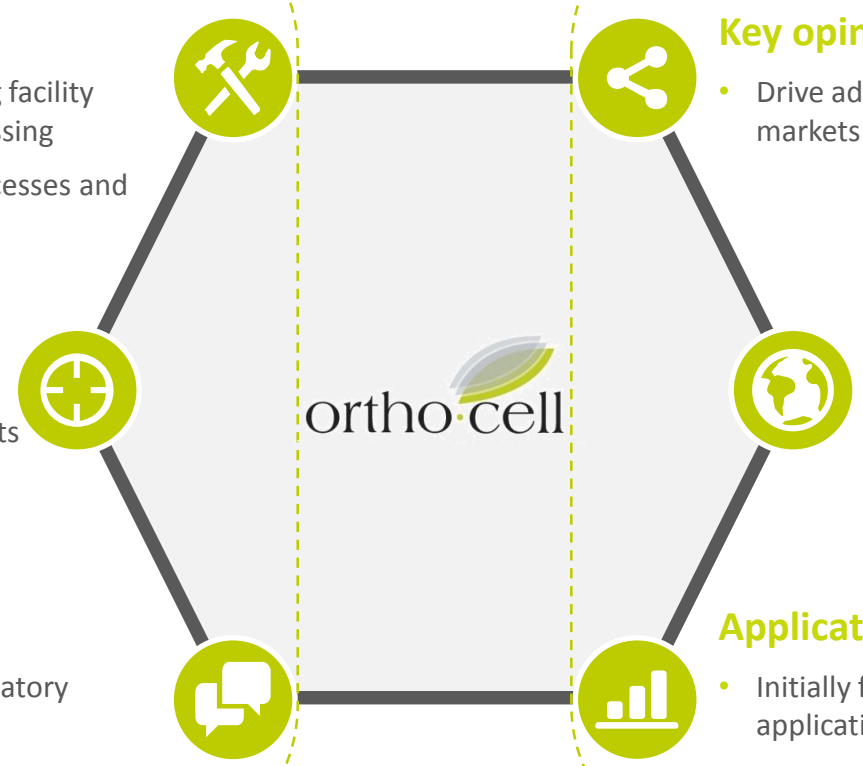
- Own and operate a manufacturing facility which underpins optimised processing
- Ensure quality manufacturing processes and scalable infrastructure in place

Clinical development

- Ensure products are fully validated
- Complete relevant studies for key products (and target applications)

Regulatory approvals

- Well defined process to attain regulatory approvals in key target markets
- Australia used as a validation platform
- Maintain strong IP protection



Commercialisation

Key opinion leaders

- Drive adoption of products in key target markets

Pathway to market

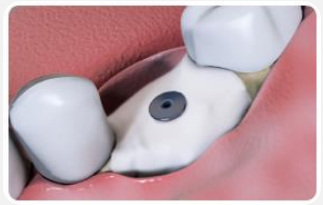
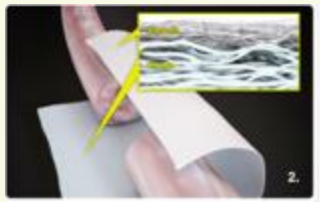
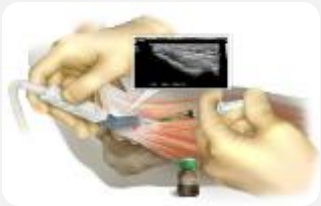
- Domestic: licensing vs. sales force
- International: develop partnerships vs. distribution model

Applications

- Initially focused on primary targeted applications
- Expansion to other relevant applications in the near to medium term

Significant market opportunity

Orthocell is at the forefront of a large and growing market opportunity in regenerative medicine in the musculoskeletal space where the addressable market is estimated to be in excess of US$10 billion p.a.

	Key focus markets		Other addressable markets[3]
CelGro® addressable markets[2]	**Dental[1]** **>US$0.6bn** ~1,500,000 procedures p.a. 	**Tendon (rotator cuff** **>US$0.9bn** ~460,000 procedures p.a. 	**Nerve[1]** **>US$1.1bn** ~700,000 procedures p.a. 
Ortho-ATI® addressable markets	**Tennis elbow[3]** **>US$4.3bn** ~1,000,000 procedures p.a. 	**Rotator cuff[3]** **>US$2.4bn** ~530,000 procedures p.a. 	**Other indications** **>US$1.0bn** Gluteal, Patellar, Hamstring & Achilles 

Orthocell is focused on addressable markets estimated to be >US$8bn with upside from further expansion into new markets, expansion of key products and development of other pipeline products

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
3. US, Japanese, European, Australian and New Zealand markets

Key products and pipeline overview

Solutions for soft tissue injuries and age related loss of function for regeneration of bone, tendon, nerve and cartilage

Ortho-ATI®

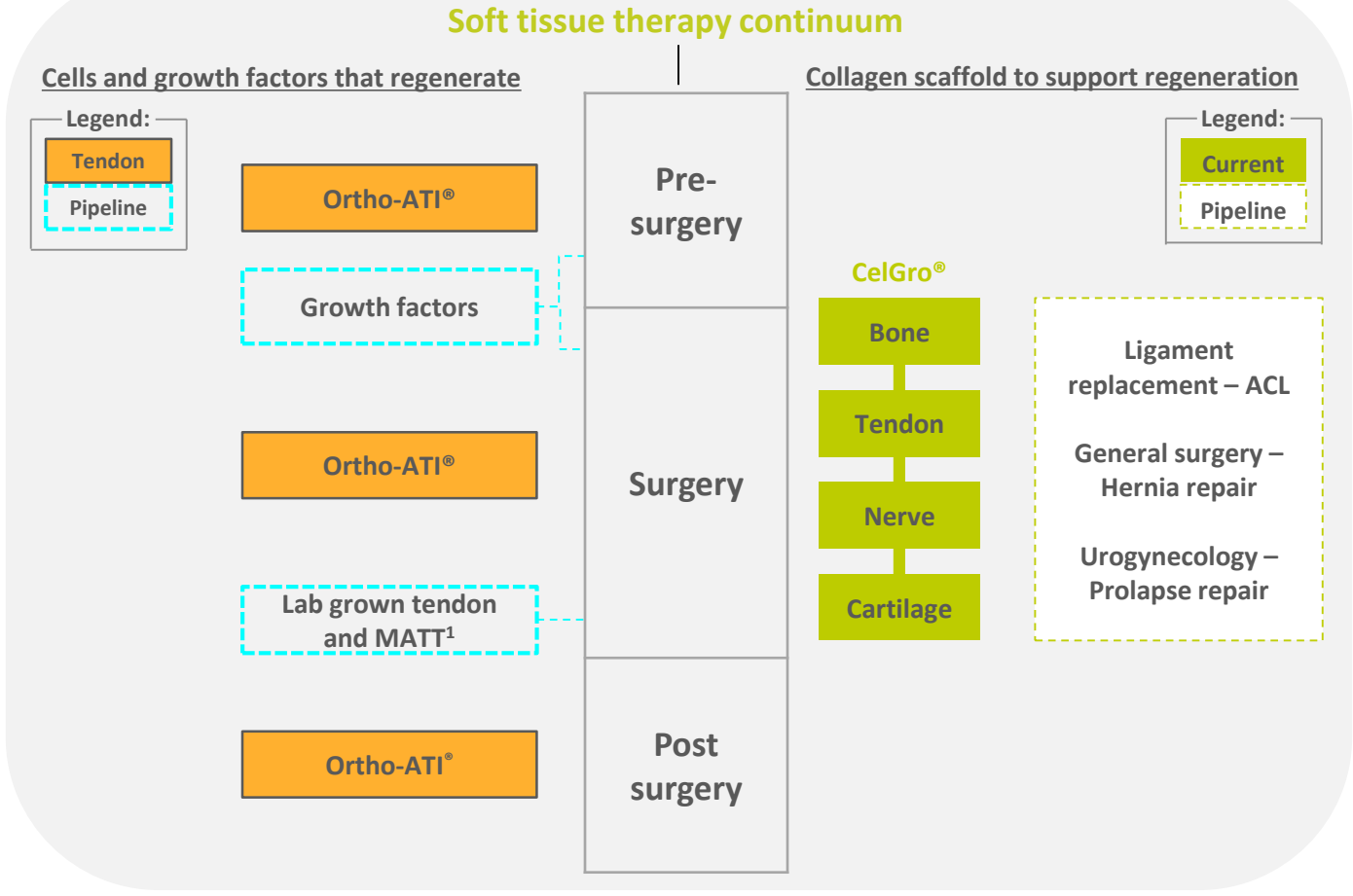
Regeneration of tendons

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

CelGro®

Tissue and bone repair

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



1. MATT: a combination product of CelGro® seeded with cells

Key product portfolio

Diversified multi-product portfolio with exciting R&D development pipeline

Diversified health care	Products	Key focus	Applications	Stages of development	Upcoming Milestones	Comments
Pure collagen medical device	CelGro®	Biological medical device for soft tissue reconstruction & repair	Dental	Discovery / Pre-clinical / Clinical	1Q CY2018	EU KOL[1] engagement; EU distribution negotiations; establish CoE[1], continue approval process (US, Aus, other)
			Orthopaedic: rotator cuff tendon, nerve & cartilage		1H CY2019	Leverage CE Mark dental approval for EU market entry Commence US approval process
			ACL ligament replacement		1H CY2018	In development, further pre-clinical animal studies to commence in 1H CY2018
	Ortho-ATI®	Tendon regeneration	Tennis elbow, gluteal, patella, Achilles & rotator cuff		1H CY2018	Completion of recruitment to J&J Ortho-ATI trial
Cell based therapies	Ortho-ACI®	Cartilage regeneration	Knee & ankle cartilage repair		2H CY2018	Optimise value opportunity through strategic partnerships in targeted regions
	R&D pipeline	"Off-the shelf" tissue repair therapies	Growth factors		1H CY2018	In development, further pre-clinical animal studies to commence in 1H CY2018
		Allogenic tendon repair	Lab grown tendon		1H CY2018	In development, further pre-clinical animal studies to commence in 1H CY2018

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

1. KOL: key opinion leader; CoE: centres of excellence

CelGro® - *Product overview*

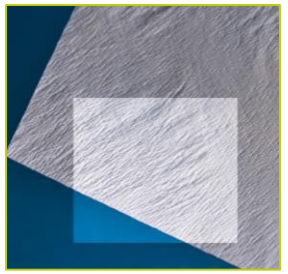
A superior medical device designed for soft tissue repair, expected to be approved in the near-term for marketing and distribution within the European Union for dental applications

What is CelGro®

- CelGro® is a medical scaffold comprised entirely of natural collagen
  - Medical scaffolds are analogous to construction scaffolds in that they provide integral support to the soft tissue whilst its undergoes repair
- Collagen medical scaffolds are widely used to augment the surgical repair of soft tissue and bone
  - A key advantage of CelGro® over other scaffolds is that it integrates with the soft tissue under repair and also degrades at the same rate as the body heals
- Manufactured inhouse by Orthocell at a quality controlled (GMP) facility in Western Australia, using proprietary SMRT™ tissue engineering process[1]
- Recently received CE mark approval for dental application
- Submitted for regulatory approval (dental application)
  - US: FDA 510(k) – approval expected in 2H CY2018

CelGro® - a versatile collagen-based scaffold

CelGro®
Regenerative medicine scaffold



Existing Applications

Bone	Tendon	Neurological	Cartilage
Provide a barrier to allow bone growth during dental implant treatment	Augments surgical repair of the rotator cuff tendon in the shoulder	Provides a nerve conduit to augment the surgical repair of peripheral nerve injuries	Augment surgical repair of articular cartilage

Pipeline

- **Ligament replacement** – *e.g. ACL surgery*
- **General surgical** – *e.g. hernia repair*
- **Urogynaelogical**

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

Bone
e.g. Dental surgery

1. Defect Site
Insufficient bone volume to anchor the dental implant

2. Bone Graft
Defect site filled with bone grafting material

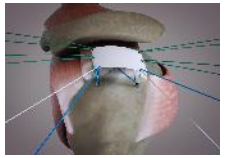
3. Apply CelGro®
Customised to size and placed over defect site to contain graft, 'guiding' bone regeneration

4. Implant Crown
Gum tissue stitched over CelGro® and Crown secured

Tendon
e.g. Orthopaedic surgery

1. Tendon Tear
Tendon detached from bone and retracted at tear site

2. Preparation of Repair Site
Torn tendon trimmed and sutures anchored in healthy bone

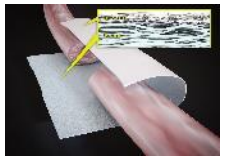


3. Apply CelGro®
Customised to size and placed over repair site to promote tendon healing

4. Reattachment
Tendon and CelGro® secured in place with sutures

Neurological
e.g. Peripheral nerve repair

1. Peripheral Nerve Injury
Nerve severed and ends retracted into wound after traumatic injury to limb



2. Preparation of Repair Site
Nerve ends located and brought to repair site without tension

3. Microsurgical Repair with CelGro®
CelGro® secured around nerve ends, forming a sealed conduit

4. Nerve Healing
Conduit protects nerve ends and enhances regeneration

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 SMRT™ 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			
Key advantages	**Biogide®**	**BioMed Extend®**	**GraftJacket®**	**Tissuemend®**	**AxoGuard®**	**Nueroflex®**		**Comments**
Proven compatibility	✓	+/-	+/-	+/-	+/-	+/-	✓	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	x	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

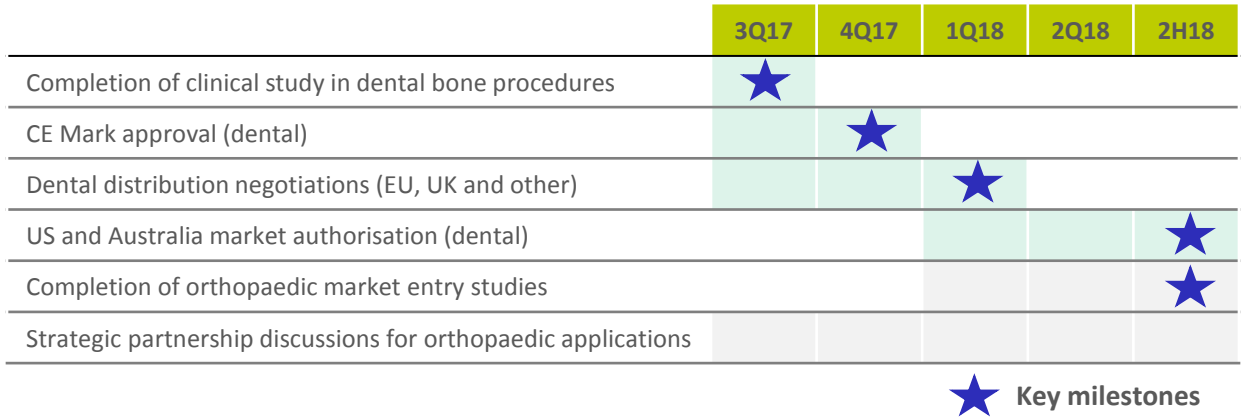
***Biogide®** currently generates €50m p.a. in dental bone graft sales in the EU alone – CelGro® has been proven, through clinical studies, to produce superior bone regeneration*

+/- No clinical data available to support characteristic required for optimal tissue repair

CelGro® - *Pathway to market*

Having received CE Mark approval for dental bone repair, CelGro® can be marketed and sold within the European Union while continuing to expand into other orthopaedic applications

Indicative commercialisation pathway (calendar year basis)



Scalable technology platform with multiple applications

Multiple application	Stage of development	*Upcoming milestones*
Dental bone repair	Commercialisation	*KOL engagement & Distribution negotiations: 1Q CY2018*
Cartilage applications	Clinical	*Recruitment complete: 2Q CY2018*
Tendon (rotator cuff)	Clinical	*Interim results: 1Q CY2018* *Recruitment complete: 2H CY2018*
Nerve applications	Clinical	*Recruitment complete: 2Q CY2018*
ACL ligament replacement	Pre-clinical	*ACL replacement in animals: 2Q CY2018*

- The CE Mark approval, for the initial application of CelGro® in dental bone applications, validates the entire technology platform
  - Endorses the clinical performance of CelGro®, quality of Orthocell's manufacturing standards, and provides a strong foundation for regulatory approval in USA, Australia and Japan
  - Orthocell can now leverage the dental CE Mark to get CelGro®'s **other orthopaedic applications to market, once clinical efficacy is established through comparative trials**
- Orthocell is actively engaging Brand Ambassadors and Key Opinion Leaders, who will be critical to drive mass market adoption
- Extensive validation already achieved to date:
  - Testimonial: Dr Brent Allan (Oral & Maxillofacial surgeon) – "***I prefer to use CelGro® over existing scaffolds… It's easy to handle and enables a high quality tissue repair***"
- Currently in discussions with a number of potential strategic commercial partners for product licensing and distribution in both Europe and other regions

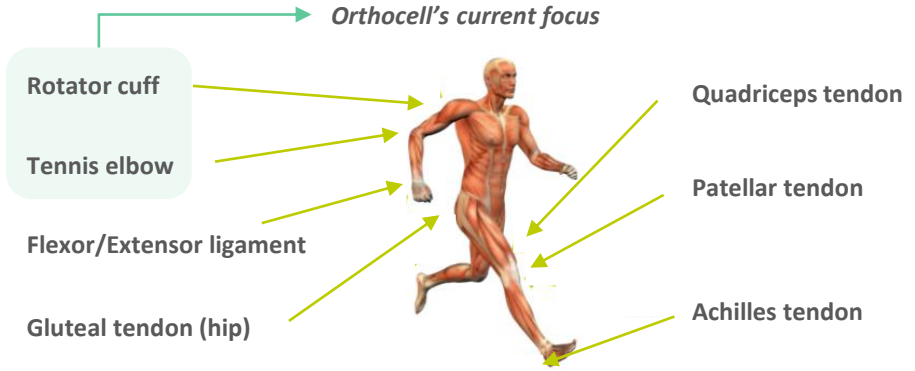
Ortho-ATI® - *Product overview*

Ortho-ATI® is a world leading breakthrough in regenerative medicine – a novel, stem cell therapy developed to treat chronic degenerative tendon injuries (tendinopathy/tendonitis), it can be utilised in both surgical and non-surgical applications

What is Ortho-ATI®

- Enables the accelerated regeneration of injured tendons, by replenishing degenerative tissue with healthy mature tendon cells (known as tenocytes)
- Safe and minimally invasive procedure for patients who fail to respond to conservative treatments (e.g. physiotherapy, Platelet Rich Plasma injection (PRP) or corticosteroids)
- Extensive clinical validation with **over 450 patient implants with Ortho-ATI® to date**
  - Published clinical data, up to 5 years post treatment, clearly demonstrating durability and efficacy as the leading tendon regeneration treatment
  - **Tennis elbow study**: 207.6% increase in grip strength (data to 4.5 years post treatment recently published in *American Journal Sports Medicine)*
  - **Gluteal tendon study:** 148.1% increase in quality of life (data to 2 years post treatment; recently submitted for publication)
- Manufactured inhouse at Orthocell's GMP-certified laboratory facility in Western Australia with TGA-approved quality systems
- **Collaboration agreement** established with DePuy Synthes Products, a subsidiary of the **global pharmaceutical company Johnson & Johnson** (NYSE:JNJ, market capitalisation: US$373.1bn) to jointly develop the novel regenerative tendon treatment

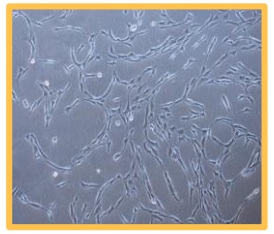
Multiple tendon applications (common injuries)



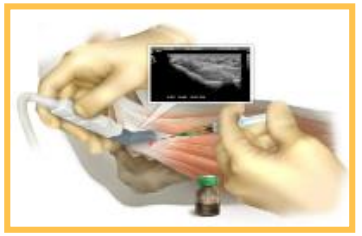
Two stage, minimally invasive, walk-in & walk-out procedure

1. **Biopsy procedure**
2. **Tenocyte (cell) cultivation**
3. **Tenocyte (cell) implantation**

Healthy tendon cells removed via minimally invasive procedure



Healthy cells grown at Orthocell's laboratory



Ultrasound guided implementation of healthy cells

4-5 week end-to-end process

Ortho-ATI® - *Key advantages (vs. traditional therapies)*

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

Comparative advantages to traditional therapies

- **Traditional therapies** only address the symptoms of tendinopathy (pain, immobility and stiffness), thus have limited long-term efficacy
- **PRP**: 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
- **Rest, physiotherapy and injections:** ineffective in the degenerative injury phase (more suited to acute injury)

	Tenocytes (Ortho-ATI®)	PRP	Corticosteroids	Surgery
Minimally invasive	✓	✓	✓	✗
Long term durability	✓	+/-	✗	+/-
Safe	✓	✓	+/-	+/-
Cost effective	✓	+/-	+/-	✗
Addresses underlying pathology	✓	✗	✗	✗

+/- No clinical data available to support characteristic required for optimal tissue repair

Ortho-ATI® - *Key advantages (vs. stem cell technologies)*

Ortho-ATI® is the only clinically proven stem cell therapy that addresses the underlying pathology of tendon damage facilitating tendon regeneration

Market positioning against alternative stem cell technologies

- **Stem cell therapies** aim to address the underlying cause of a disease/condition
  - Tenocytes (Ortho-ATI®) are the only clinically proven stem cell therapy that address the underlying cause of tendinopathy and repair the tendon
- Ortho-ATI® is significantly ahead of the competition and cannot be easily replicated
  - **Patent protected in major global jurisdictions**, including USA, China, Singapore, Hong Kong and New Zealand
  - **Optimised manufacturing** processes
  - **Extensive data** on purity, potency and identity of cell therapy

	Tenocytes (Ortho-ATI®)	Dermal fibroblasts	Embryonic stem cells	MSC (umbilical cord)[3]	MSC (other[3])
Homologous[1]	✓	✗	✗	✗	✗
Autologous[2]	✓	✓	✗	✗	✓
Proven efficacy	✓	?	?	?	?
Proven durability	✓	?	?	?	?
Commercially available	✓	✗	✗	✗	✗

1. Homologous: the treatment of a recipient's cells or tissues with cells that performs the same basic function or functions in the recipient as in the donor
2. Autologous: undifferentiated treatment cells are obtained from the same injured individual into whom they are reimplanted as part of the treatment
3. MSC: mesenchymal stem cells; 'Other' refers to MSC for blood, fat and bone marrow

Ortho-ATI® - *Path to market*

Market leading product with a validated pathway and attracting the attention of large global partners

- ✓ **Clinical validation –** *Over 450 patient implants with Ortho-ATI®*
- ✓ **Optimise manufacturing capability –** *GMP-certified/TGA licensed facility*
- ✓ **Treatment pathway validated –** *Australian Key Opinion Leader network established and already referring patients for treatment*
- ✓ **Establish a project partner –** *Collaboration agreement with Johnson & Johnson (J&J)*
- ✓ **Target prospective licensing partners and key opinion leaders**
- ○ **Attain regulatory approval in key markets**

Indicative commercialisation pathway (calendar year basis)

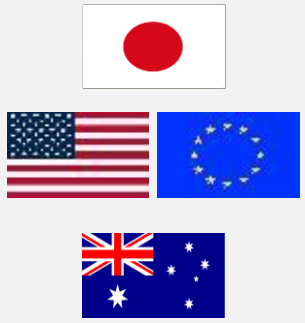
	4Q17	1Q18	2Q18	2H18	1H19
Pre Investigation New Drug meeting with FDA		★			
Discussion on distribution / licensing agreements (AUS)	★				
J&J rotator cuff clinical trial recruitment			★		
Workers compensation study publication			★		
Ortho-ATI® vs. surgery trial recruitment				★	
J&J rotator cuff clinical trial interim results analysis				★	
Potential USA / Australian licensing agreement					★

★ **Key milestones**

Johnson & Johnson INNOVATION

- ✓ Collaboration agreement signed in **January 2017**
- ✓ **Co-funded study commenced in May 2017**, designed to support a US pivotal study
  - 30 patient, randomised, controlled study comparing Ortho-ATI® to corticosteroid injection for the treatment of rotator cuff tendinopathy
  - Trial led by Professor Allan Wang, President of Australian Elbow and Shoulder Society
- ✓ Ortho-ATI® is a market leading therapy and would be highly complimentary to DePuy Synthes' comprehensive portfolio of orthopedic and neuro products, as well as musculoskeletal, reconstructive and therapeutic services

Targeting key global markets



- ✓ In advanced discussions with a potential Japanese distribution partner to leverage abridged approval process
- ✓ In advanced discussions with potential US & EU distribution partners
- ✓ Australia has been used as the platform for clinical validation
- ✓ Small internal sales team; leverage other distribution partnerships

Ortho-ATI® - *Development pathway*

Orthocell is currently focused on completing current clinical studies and continuing strategic discussions

Ortho-ATI® development pathway

Stage	Purpose
Discovery / preclinical testing	✓ *Discovery of an unmet clinical need* ✓ *Completed preclinical testing*
Clinical trials	✓ *Safety & tolerability* ✓ *Efficacy – comparison to existing market interventions* ❑ *Pre-IND meeting with the FDA to confirm approval trial clinical requirements* ❑ *Approval trial – in-country trial for US regulatory approval*
Regulatory registration	❑ *Regulatory approval (FDA and/or CE mark)*
Monitoring	❑ *Post market – monitoring of intervention effectiveness*

Development pathway overview

- Ortho-ATI® is substantially **de-risked** from an evidence and manufacturing based perspective – Australia used as a validation platform
  - 6 key clinical studies completed and 5 years of post-treatment clinical data collected
- **Placebo controlled testing is not required** due to significant ethical issues in conducting a placebo treatment on patients at the end of the treatment spectrum
- Efficacy established through clinical trials followed by post market surveillance
- Post the current clinical trial being undertaken with J&J, Orthocell (and/or J&J) will complete a market entry designed study

The Orthocell and J&J collaboration significantly de-risks the development of Ortho-ATI®

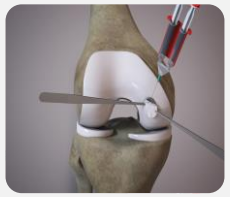
Ortho-ACI® and R&D pipeline

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**
- **>380 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**

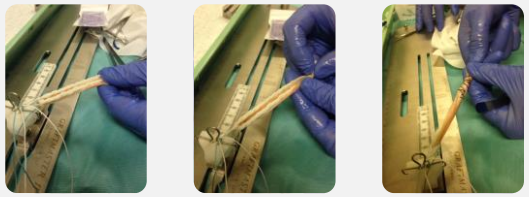


Ortho-ACI® procedure

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)



ACL ligament replacement

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

Leverage existing knowledge towards human clinical trials

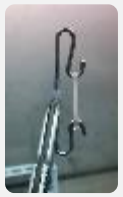
- Cell factory-derived tissue specific growth factors **to augment bone, cartilage and tendon repair**
- Part of successful **international collaboration**[2] – multiple animal studies completed and published
- "Cell Factory" **patents granted in key jurisdictions** (USA and Europe)

Lab grown tendon

Lab grown tendons

Next generation product to complement Ortho-ATI®

- **Successfully manufactured** human tendon in a laboratory
- **Ongoing collaboration** with academic researchers[1] (received **ARC linkage grant**)
- Significant **unmet patient needs** and **multiple applications** (i.e. hand, shoulder and hamstring)



Growth factor samples

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)

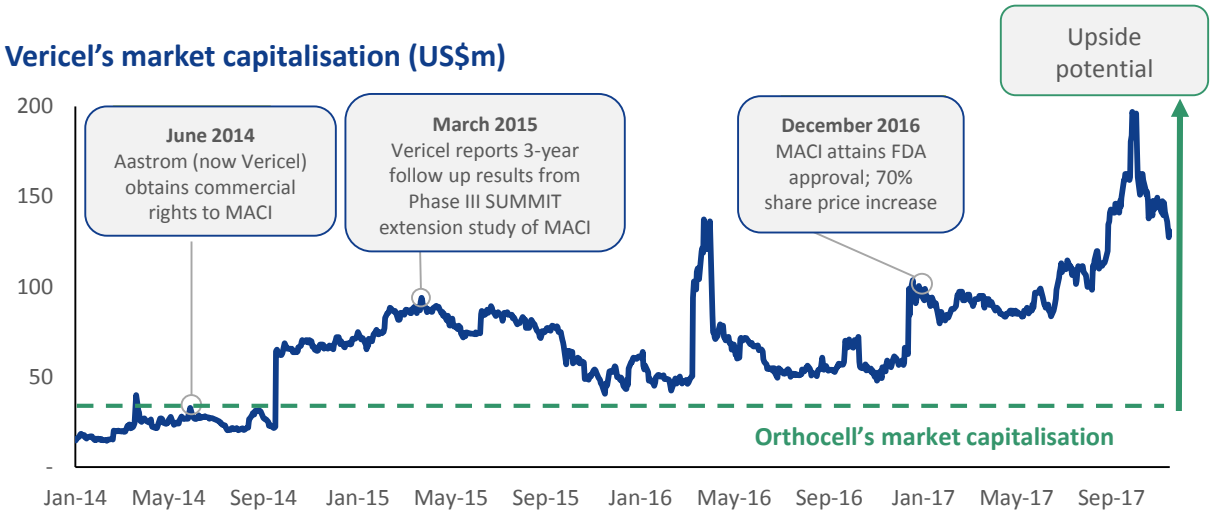
Vericel case study highlights Orthocell's valuable portfolio

Significant upside potential exists for Orthocell's product portfolio which addresses a range of tendon, cartilage and soft tissue injuries

- Vericel is a US company that develops, manufactures, and markets two autologous cell therapies:
  - Epicel®: cultured epidermal autografts
  - MACI®: autologous chondrocytes on porcine collagen membrane
- MACI® was the first FDA approved product to grow cells on scaffolds using healthy cartilage tissue from the patient's own knee

	Orthocell	Vericel	Commentary
ACI stem-cell product (cartilage focus)	✓	✓	MACI® is Vericel's commercialised ACI product for knee, Ortho-ACI® is the next generation of this technology
ATI stem-cell product (tendon focus)	✓	x	Orthocell's Ortho-ATI® in clinical stage, **collaboration discussions with Johnson & Johnson** expected to commence 1H CY2019
Platform technology (Collagen medical device for multiple uses)	✓	x	CelGro® has received EU regulatory approval and serves as a **platform** for developing **future approaches to soft tissue repair**

Vericel's market capitalisation (US$m)



- ✓ Orthocell has a **superior 3rd generation** ACI product for cartilage repair
- ✓ Orthocell also has the **world's first cell therapy for tendon repair** – a much larger addressable market than cartilage
- ✓ Orthocell also CelGro® which address unmet needs in multi-billion dollar markets
- ✓ **Significant upside potential exists** considering Orthocell's diversified multi-product portfolio of cell therapies and regenerative medicine products

Upside potential underpinned by recent transactions

Significant upside potential in Orthocell based on recent transactions executed in the regenerative medicine and medical scaffold sectors

Deal date	Deal type	Licensee/ Acquirer	Licensor/ Target	Phase	Transaction value[1]
Dec 16	Corporate	Allergan	LifeCell	Commercial	US$2.9bn
May 12	Corporate	DSM	Kensey Nash	Commercial	US$0.4bn
Jan 14	Asset	Organogenesis Inc.	Shire	Commercial	US$0.3bn
Oct 17	Corporate	smith&nephew	rotation medical	Commercial	US$0.2bn
Mar 15	Corporate	FUJIFILM Holdings Corporation	Cellular Dynamics International	Commercial	US$0.3bn
Jul 15	Corporate	TiGenix Living Medicines	coretherapix	Phase II	US$0.3bn
Apr 15	Strategic ownership stake / asset rights	Celgene	mesoblast the regenerative medicine company	Multiple in Phase III	US$45m
Jan 17	Strategic ownership stake / asset option	FUJIFILM Holdings Corporation	cynata therapeutics	Phase I	US$51m
Dec 16	Licensing (Japanese market)	AGC Asahi Glass	regeneus living regenerative medicine	Completed Phase I	US$17m

Medical scaffold transactions

Regenerative medicine transactions

Japanese cell therapy licensing

Orthocell market capitalisation

1. Transaction value is the estimated transaction value based on the combination of cash and/or script consideration, upfront payments and any milestone payments agreed upon

Rotation Medical case study

The recent US$210m acquisition of Rotation Medical, by Smith & Nephew, demonstrates significant upside potential for Orthocell in the regenerative medicine space

- In October 2017, Smith & Nephew announced they would **acquire Rotation Medical for up to US$210m**
  - US$125m upfront, US$85m in instalments over 5 years (subject to financial milestones)
- Smith & Nephew (LON:SN, Market Cap: £11.8bn) is a multinational medical equipment and technology company
- Rotation Medical is a private medical scaffold company **focused on rotator cuff repair**
  - Its Rotator Cuff Repair System is a collagen-based bioinductive implant derived from bovine tendon
  - Implant has been shown to heal rotator cuff tendon by inducing the growth of new tendon-like tissue
  - Commercially available having earnt FDA 510(k) clearance in 2014 for sale in the US, with a filing being prepared for EU approval

	Orthocell	Rotation Medical	Commentary
Tendon regenerative therapy	✓	✓	• Orthocell's CelGro® is a biological medical scaffold to augment the surgical repair of damaged tendons • Rotation Medical is focused on developing a medical scaffold for rotator cuff tendon repair
Platform technology	✓	✗	• Orthocell's CelGro® is easily customisable with multiple applications (i.e. bone, tendon, nerve and cartilage) • Rotational Medical's medical scaffold is only focused on a single application (i.e. rotator cuff tendon)
Multiple products	✓	✗	• Orthocell's product portfolio includes CelGro®, Ortho-ATI® and Ortho-ACI and multiple pipeline products • Rotation Medical only has one product in its portfolio
Global regulatory approval	✓	✓	• Orthocell's CelGro® is approved in EU and Ortho-ACI® is approved in Australia • Rotation Medical received FDA clearance for sales in the US and are preparing for EU approval

Upcoming catalysts

Significant operational milestones expected over the next year as Orthocell continues to develop its product portfolio

	2017	2018 onwards
CelGro®	• Dental study completion and publication submission • Explore strategic partnerships and distribution opportunities (i.e. EU partner/distributor for dental application)	• Recognition of (dental) CE Mark in Hong Kong and Taiwan • Complete other (dental) regulatory applications (i.e. US and Australia) • Interim trial results for tendon, cartilage and nerve studies • Commence market entry studies (dental, tendon and nerve) for US and Australia • Progress regulatory applications for tendon and nerve in Europe, US and Australia • Explore strategic partnerships and distribution opportunities
Ortho-ATI®	• Advance US tendon and ligament regulatory process • Explore commercialisation and distribution opportunities (US and Japan)	• Collaborative J&J rotator cuff study – interim results • Ortho-ATI® vs. surgery for tennis elbow – interim results • Publish worker compensation retrospective study • Explore commercialisation and distribution opportunities (US and Japan) • Progress key market regulatory approval submissions
Ortho-ACI®	• Explore commercialisation and distribution opportunities (US and Japan)	• Explore commercialisation and distribution opportunities (US and Japan)

Appendix

Board of Directors, IP portfolio and further product slides

ortho·cell

Board of Directors

Dr Stewart James Washer

Chairman

- 20 years' CEO and board experience in medical technology, biotech and agri-food companies
- Executive Director of Zelda Therapeutics (ASX:ZLD) and Minomic International, Director of Cynata (ASX:CYP)
- Previous Board positions include Chairman of Hatchtech Pty Ltd that was sold in 2015 for A$279m and was a Director of iCeutica that was sold to a US Pharma. He was also a Senator with Murdoch University and was a Director of AusBiotech Ltd

Commercialisation
IP management
Corporate

Paul Anderson

Managing Director

- 20 years' experience in medical device and cellular therapeutic fields, with intimate knowledge of regenerative medicine
- Expertise in commercialising emerging R&D technologies and in the establishment of GMP manufacturing facilities
- 15 years' experience in CEO and board roles, including as former MD of Verigen Australia, the developer of the 1st generation ACI treatment

Regenerative medicine
Regulatory and clinical
Manufacturing

Matthew Callahan

Non-Executive Director

- 20 years' legal, IP and investment management experience
- Developed 3 FDA approved products
- Founding CEO of iCeutica and Churchill Pharmaceuticals
- Investment Director at 2 venture capital firms
- Current Executive Director of Botanix Pharmaceuticals (ASX:BOT)
- Co-founding director of Orthocell and led initial VC investment

Corporate
Regulatory and clinical
IP and legal

Professor Lars Lidgren

Board Member

- Professor in Orthopaedics at the University Hospital of Lund
- Leads a productive regenerative medicine research group at the University Hospital of Lund
- Founded multiple biotechnology companies (Scandimed, Bone Support, AMeC and GWS)

Regenerative medicine
Research & development

Mr Qi Xiao Zhou

Board Member

- 15 years' experience in China as a senior business manager and executive
- General Manager of Shenzhen Lightning Digital Technology
- Experience within public markets of Hong Kong, China and Taiwan
- Business management and development experience in Asia

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 14years experience in coordination of qualification systems, quality system management, and significant regulatory experience (ISO, TGA, FDA)

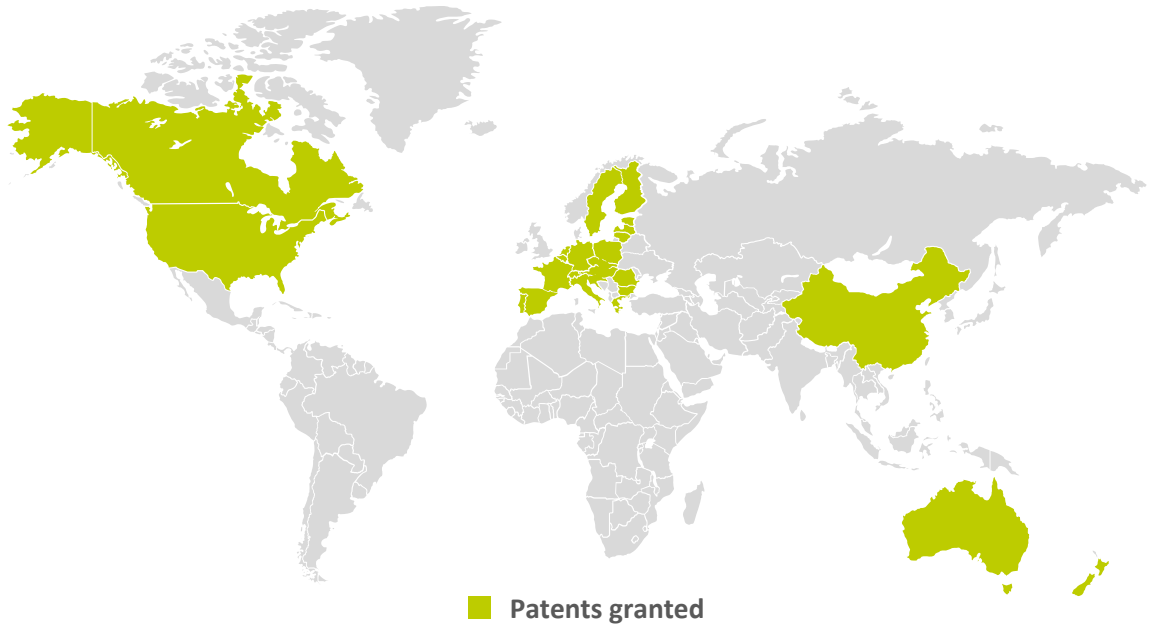
IP portfolio and strategy

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

Overview

- Orthocell is focused on maintaining patent protection for its leading manufacturing technologies and treatment processes
- Orthocell maintains an active program of patenting, with ownership of 27 granted patents across the Ortho-ATI®, Ortho-ACI® and CelGro® technologies, and related methods of treatment and manufacturing
  - Patents granted and applications also cover pipeline products such as the 'Cell Factory' technologies and 'Sutureless Repair of Soft Tissue"
- Orthocell 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

Patents granted in major global jurisdictions



CelGro® - *Clinical trials completed & 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
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
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	Awaiting ethical approval

Ortho-ATI® - *Clinical studies completed to date*

Ortho-ATI® has been significantly de-risked from an evidence based perspective, with clinical efficacy having been demonstrated through numerous clinical trials

- ***NOTE:*** *Patients involved in clinical trials had failed all other treatment alternatives (e.g. physiotherapy, at least 1 corticosteroid injection)*

Study ID	Description	Implant site	Duration (months)	Avg. symptom duration (months)	Key outcomes	Publication status
ATI-001	Pilot study of Ortho-ATI® in severe, chronic, resistant lateral epicondylitis *(tennis elbow)*	Lateral epicondyle (elbow)	60	31	• MRI studies showed tendon regeneration at 12 months, sustained to 4.5 years • +207% in grip strength post treatment	6 month data abstract 1 year data published 4.5 year data published
ATI-002	Pilot study of Ortho-ATI® in gluteal tendinopathy *(hips)*	Gluteal tendon (hip)	24	33	• Significant clinical improvement in pain and function scores at 24 months • No persistent complications from procedure	Published
ATI Case Study 1	Novel treatment for partial-thickness rotator cuff tear and tendinopathy in an elite athlete	Rotator cuff (shoulder)	10	12	• Substantial improvement in pain and function • MRI studies showed complete resolution of tendon tear • Elite athlete was able to return to national-level competition after treatment	Published
ATI Case Study 3	A novel treatment for recalcitrant patellar tendinopathy	Patellar tendon (knee)	9	10	• Patient able to return to heavy manual labour job after treatment • MRI scans taken at 6 months after treatment showed resolution of tendinopathy	Unpublished
ATI Case Study 2	Treatment resistant tendinopathy of the patellar tendon	Patellar tendon (knee)	5	24	• Improvement in knee function and pain observed after 5 months • MRI studies at 5 months showed significant reduction in tendinopathy and size of tendon tear	Unpublished
Retrospective Study	Ortho-ATI® for the treatment of compensating occupationally related later epicondylitis: A Retrospective Case Study	Lateral epicondyle (elbow)	Various	22	• ↓ pain in the affected limb by ~90% at rest and ~54% with usage at time of assessment • 88% of patients were able to return to work	Unpublished

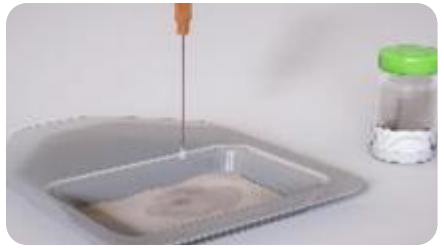
Ortho-ACI® - *Product overview*

Gold standard Autologous Chondrocyte Implantation which offers a customised approach to treat articulating cartilage defects

- Articular cartilage provides a smooth, lubricated surface for low friction movement of joints
- Defects in cartilage occurs through injury or wear and tear and leads to increasing joint pain and impaired mobility
- Unlike other tissues, cartilage fails to repair itself effectively
  - Ortho-ACI® leverages autologous and homologous cell therapy to regenerate cartilage
- Market for cartilage repair is large and growing
  - Approximately 900,000 people develop cartilage disease each year in the US alone
  - 60% of the 70,000 arthroscopies conducted in Australia are estimated to be due to localised loss of cartilage
- Over 380 patient implants have been treated with Ortho-ACI® to date in Australia, Hong Kong and Singapore
- Having already received Australian approval for manufacturing and marketing, a low capital approach will be used to commercialise Ortho-ACI® globally

Ortho-ACI® utilises a two-stage surgical process to treat symptomatic defects of articulating cartilage

1. Chrondrocytes are isolated from healthy cartilage collected from each patient via a biopsy, cultured then loaded into CelGro® scaffolds in theatre



2. After debridement and cleaning of the cartilage defect site, scaffold is placed cell-side down over the defect and secured with fibrin glue

Rehabilitation occurs over 12 weeks, with patients able to return to sport after 6-12 months (patient dependent)

Ortho-ACI® - *Market positioning*

Ortho-ACI® has significant competitive advantages to 1st generation ACI techniques and other technologies for the repair and regeneration of articular cartilage

Evaluation Criteria	1st Generation ACI	3rd Generation Ortho-ACI®
Invasiveness of procedure	× Requires a large surgical incision × Periosteal flap harvested and sutured over defect to contain cells	✓ Delivered arthroscopically through a small incision ✓ Scaffold and cells combined
Control of cell density	× Lack of control over cell quantity delivered to patient	✓ Customised per patient delivering a targeted cell quantity
Quality of outcome	× Use of periosteal flap can lead to post operative complications	✓ Seeded collagen is proven as safe and well tolerated
Cost effectiveness	× Long operation time and high current patient costs	✓ Reduces product wastage and cultivation time, minimising costs

Evaluation Criteria	Microfracture	3rd Generation Ortho-ACI®
Maintenance of subchondral bone integrity	× Drills into bone to facilitate marrow stimulation which may lead to complications	✓ Maintains integrity of bone to deliver superior outcomes
Infill generated	× Generates fibrocartilage infill	✓ Generates high quality hyaline cartilage
Suitability for lesions >2cm2	× Not recommended for lesions >2cm2	✓ Gold standard for lesions >2cm2
Durability of repair	× Less durability of repair	✓ Longer durability of repair

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