ortho·cell

Advancing Repair and Regeneration

Investor Presentation
ASX: OCC
August 2014

Paul Anderson
Managing Director

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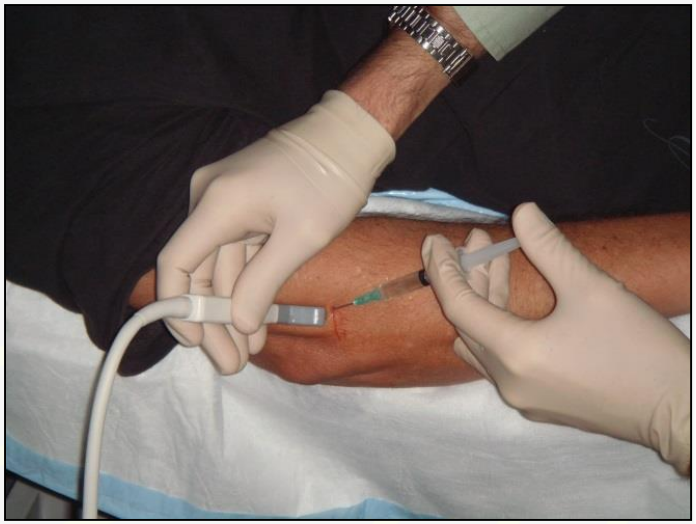
About Orthocell

Orthocell is a commercial stage regenerative medicine company



Orthocell's lead product, Ortho-ATI™, uses cell therapy to repair and regenerate damaged tendons and ligaments

IPO details

Amount Raised	$8 million
Price per Share	$0.40
Shares on issue at completion of the Offer	82,500,000
Post-IPO market cap	$33 million
Options outstanding	5,912,500 (exercise price $0.50)
ASX code	OCC

	Shareholder	% following Full Subscription
Major Shareholders	Stone Ridge Entities	12.34%
	Paul Anderson	8.44%
	Ming Hao Zheng	8.56%
	Qi Xiao Zhou	7.22%
	Jia Xun Xu	6.26%
	Australian Super	5.60%

Investment Highlights

Approved treatments with strong clinical evidence	First tendon and ligament regeneration product approved in a major market and the next generation cartilage repair therapy
Significant unmet medical need	Musculoskeletal conditions are the leading contributor to Australia's disability burden and existing treatments don't address the underlying injury or disease
TGA approved manufacturing facility	Commercial manufacture ongoing in TGA approved cGMP facility
Next product in late stage development	Novel collagen scaffold for repair of tissue planned for registration application in Q2 2015
Global approvals and expansion underway	Expansion of existing approvals to other international markets underway and first product licensed to China
Team with track record	Team secured approval of Australia's first cell therapy and Board has relevant M&A and licensing experience

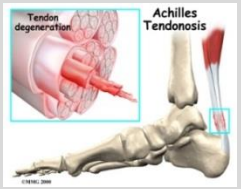
Experienced leadership team

Paul Anderson	CEO	Verigen, Genzyme, Biomet
Prof Ming Hao Zheng	CSO	Verigen, Genzyme, UWA
Dr Stewart Washer	Exec Chair	Cynata, Minomic
Matt Callahan	Director	iCeutica, Glycan Bio, Dimerix, Scanalyse
Prof Lars Lidgren	Director	UN Bone & Joint Chair, Biomet, University Lund

Company History

- 2006/7 – Incorporation, seed capital, cGMP manufacturing facility completed
- 2008/9 - TGA license, Ortho-ATI™ tennis elbow clinical study commenced
- 2010 - Ortho-ATI™ first paying patients treated in Australia
- 2011 - Ortho-ATI™ European Achilles tendon trial study commenced
- 2012 – First Ortho-ATI™ clinical data released
- 2013 - Ortho-ATI™ European Achilles tendon trial last patient treated
- 2014 – First CelGro™ ear drum clinical trial commenced

Three complementary platforms

	Ortho-ATI™	CelGro™	Ortho-ACI™
			
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Large market for tendon repair

- **Tendon injury is very common, particularly in active people:**
  - Over 250,000 rotator cuff injuries need surgery in the US each year
  - Tennis elbow affects 1%-3% of the population
  - Over 200,000 Achilles tendon sports injuries in the US each year
- **Effectiveness of existing treatments has been limited:**
  - Surgery – stitching tendons back together for biomechanical support (not healing)
  - Tendon graft – reconstruction provides only partial restoration of activity
  - Enriched plasma/needling – minimal supporting clinical evidence
- **No well established cell-based therapy:**
  - Viability of cell-based approach established
  - Mesenchymal stem cells are unproven with risk of ectopic bone formation
  - Tendon cells (*Tenocytes*) very difficult to grow and require specific culture conditions

Regenerating and repairing tissue - not just treating symptoms

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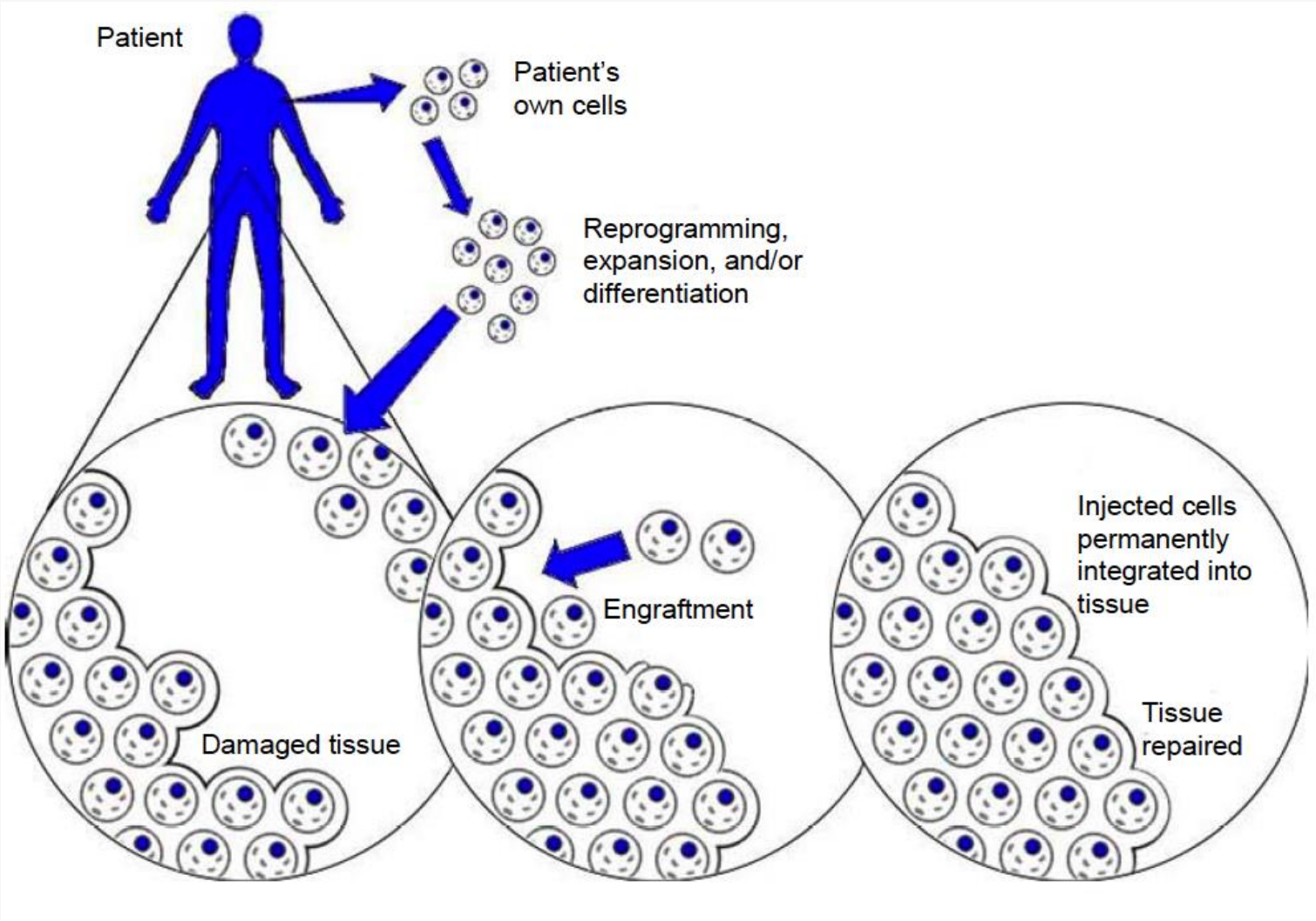
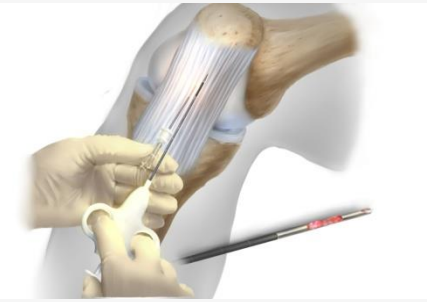
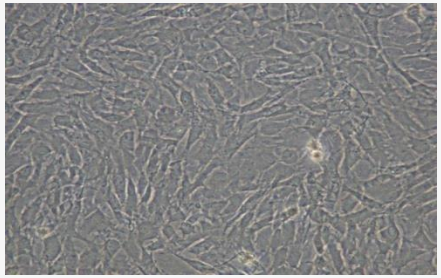
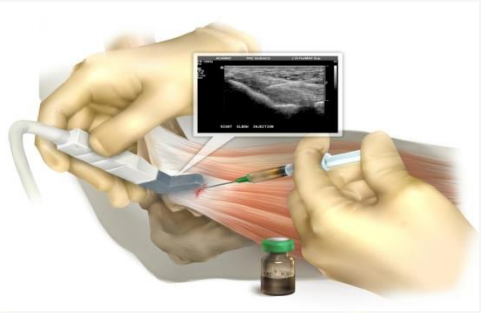


Ortho-ATI™ - tendon regeneration

Proprietary method for expanding and cultivating tendon stem cells (*Tenocytes*)





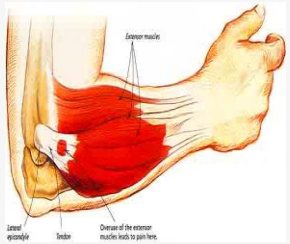


Tendon biopsy from patient → GMP process to expand and cultivate patient's cells → Re-inject tenocyte cells at site of tendon injury

ATI = autologous tenocyte implantation

Ortho-ATI™ - multiple indications

Rotator Cuff

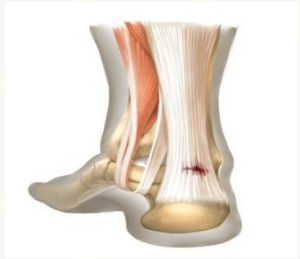


Tennis elbow

Gluteal Tendon

Hamstring Tendon

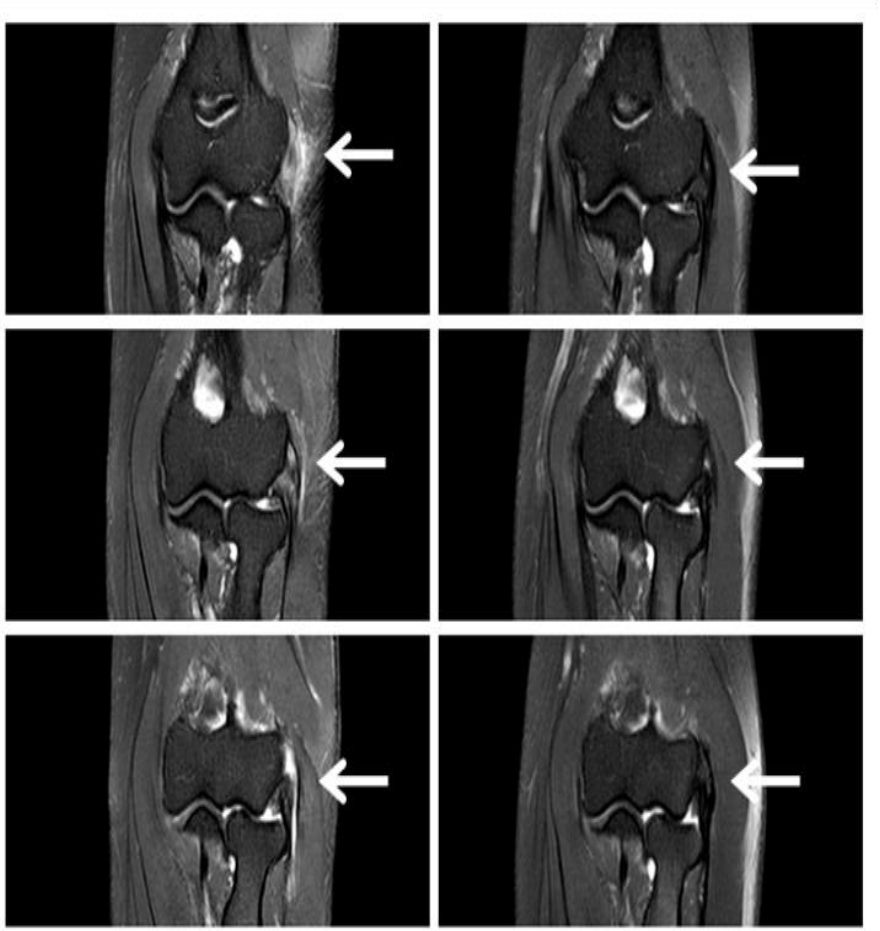
Patellar Tendon



Achilles Tendon

Ortho-ATI™ - three trials completed

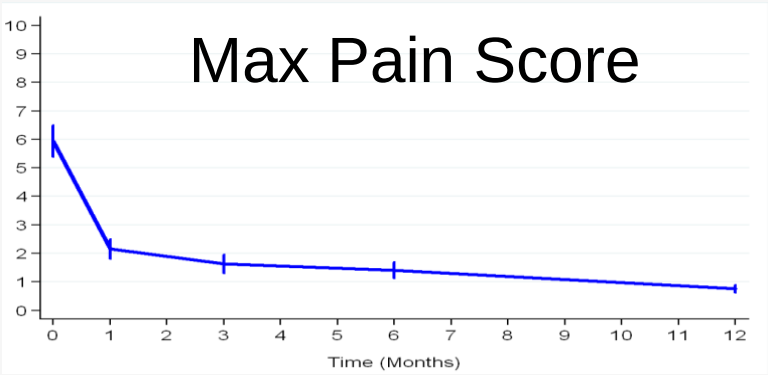
- **ATI Tennis Elbow (2008)**
  - 20 patient prospective study
  - Published (2013) in the prestigious *American Journal Sports Medicine*
- **ATI Gluteal Tendon (2010)**
  - 15 patient prospective study
  - In preparation for publication
- **ATI Rotator Cuff (2011)**
  - Elite gymnast study
  - Published (2013) in *British Medical Journal*

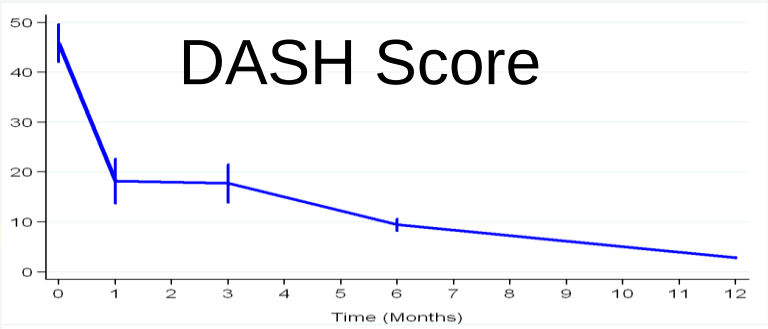


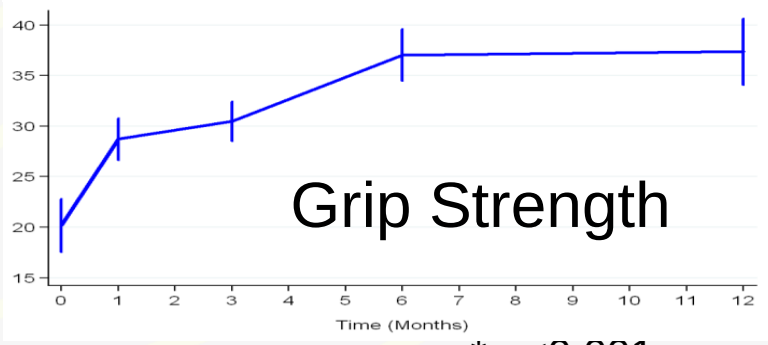
Tennis elbow trial data

Key Findings:

- 87% mean improvement in Max Pain Score
- 93.7% mean improvement in DASH Score
- 85.3% mean improvement in Grip Strength







* p<0.001

Patient feedback

Amanda Redwood

43 year old mother of two with resistant tennis elbow. Before treatment even basic tasks such as lifting a glass of water were painful and required the wearing of a brace.

"Now I can do anything that I want as if I never had the injury."

Sean Harrup

28 year old amateur footballer treated for resistant patella tendinopathy.

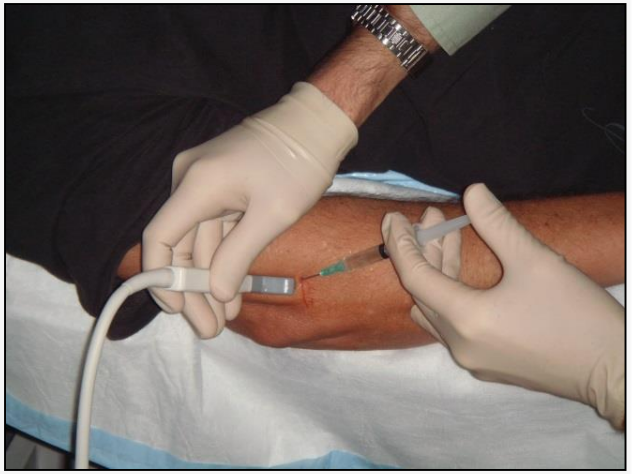
"I got to the point were I thought I would never play again. I had the injection in December 2012 and started training in January 2013 and have not missed a game this year."

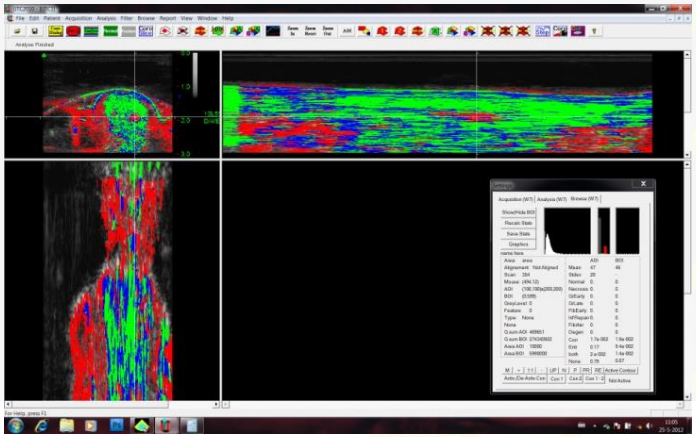
"It's amazing what they can do now. It's a rare procedure for a common injury."

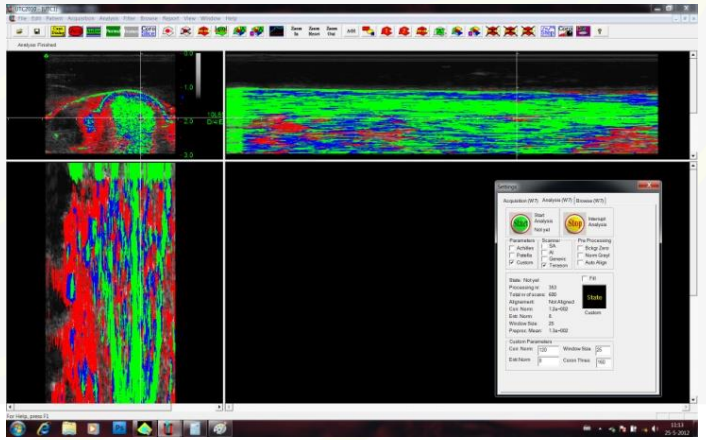
Ortho-ATI™ - ongoing clinical trial

Achilles Tendon Trial (completes Q2 2014)

- 90 patients double-blinded, placebo controlled randomised trial (1:1)
- first placebo controlled, randomised tenocyte trial undertaken globally
- half patients receive Ortho-ATI™ injection and half receive saline
- all patients now treated, with last patient last visit for 6 month review due in July 2014
- top line data expected end Q3 2014

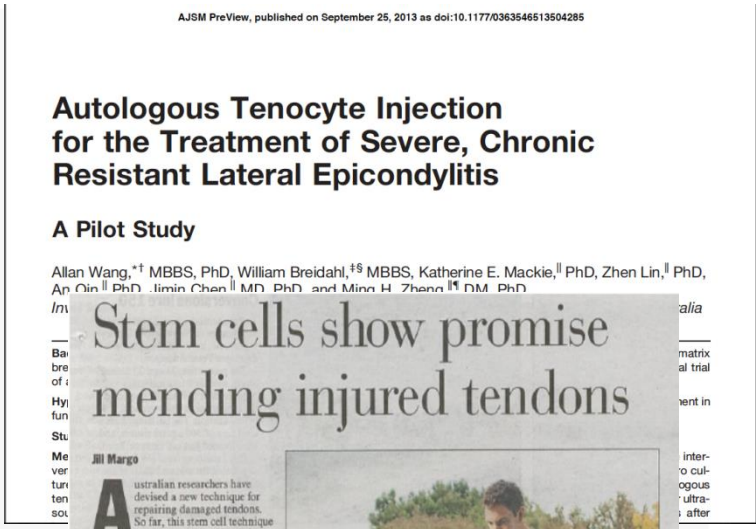






Ortho-ATI™ - further clinical trials

- **Tennis elbow trial (commences Q3 2014)**
  - Patients with severe lateral epicondylitis
  - Ortho-ATI™ injection
  - Pain and function outcomes with MRI assessment at 6 and 12 months
- **Patella tendon trial (commences Q4 2014)**
  - Patients with tendinopathy
  - Ortho-ATI™ injection
  - Pain and function outcomes with ultrasound assessment at 6 and 12 months
- **Gluteal Tendon Trial (commences Q4 2014)**
  - Prospective study
- **Rotator Cuff Trial (commences Q2 2015)**
  - Prospective study


AJSM PreView, published on September 25, 2013 as doi:10.1177/0363546513504285

Autologous Tenocyte Injection for the Treatment of Severe, Chronic Resistant Lateral Epicondylitis

A Pilot Study

Allan Wang,*† MBBS, PhD, William Breidahl,†§ MBBS, Katherine E. Mackie,‖ PhD, Zhen Lin,‖ PhD,

Stem cells show promise mending injured tendons

Jill Margo

Australian researchers have devised a new technique for repairing damaged tendons. So far, this stem cell technique has been used on 100 patients with promising results.

Ninety of them reported a 60 per cent or higher improvement rate in the use of their damaged joint.

This particular use of stem cells is thought to be a world first and a major trial of the technology is now under way in the Netherlands.

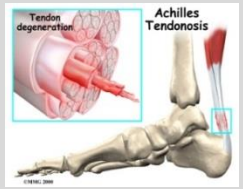
While other tendon therapies tend to treat the symptoms, this aims to treat the cause of the symptoms.

Tendons are tough bands of tissue that connect muscle to bone. Some develop micro tears and begin to degenerate, causing pain and weakness. Age and weight can affect them, as can

Ortho-ATI™ - Marketing Strategy

- **Ramp up product sales**
  - already revenue generating in Australia – 200+ patients treated as part of early commercialisation efforts
  - new channel to radiologists, sports docs and physio's
  - sales tools, marketing and referral networks expansion
- **Expanded clinical program**
  - drives indication expansion and evidence base
  - supports reimbursement applications in Australia
- **International regulatory approval**
  - Application planned for Europe or Japan following ARTG registration
- **Maintain regulatory license**
  - License to manufacture from TGA in place – additional approvals lodged for ARTG registration

Three complementary platforms

	Ortho-ATI™	CelGro™	Ortho-ACI™
			
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Current Applications	Tennis Elbow, Achilles, Gluteal, Patellar, Rotator Cuff	Tympanic membrane (ear drum)	Knee and ankle
Future Applications	Quadriceps, Hand, Hip Capsule	Cartilage and tendon repair, hernia, vaginal wall and other general surgical repairs	Knee and ankle
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Approval Status	TGA Approved and application register on ARTG lodged	Registration application planned Q2 2015	TGA Approved and application register on ARTG lodged

CelGro™ Collagen Scaffold

CelGro™ is a collagen derived scaffold that can be used for orthopedic (Ortho-ATI™ or Ortho-ACI™) and other soft tissue regeneration

- CelGro™ is manufactured using a proprietary technology that gives it unique properties:
  - high mechanical strength
  - highly pliable
  - high purity (non-inflammatory)
  - porous and multi-surfaced
  - cell friendly
- CelGro™ has a number of significant advantages over synthetic and other collagen derived scaffolds

CelGro™ Collagen Scaffold

- Multiple applications:
  - ear drum – reconstructive
  - orthopaedic - bio-mechanical support and/or cell delivery
  - gynaecological / urological – reconstructive
  - general surgical – reconstructive
- Ear drum repair Phase 1 clinical study underway
- Application for Australian ARTG registration planned for Q2 2015
- EU, Japan and US approvals planned after ARTG registration
- Global distribution partnerships will be pursued for different applications

Three complementary platforms

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	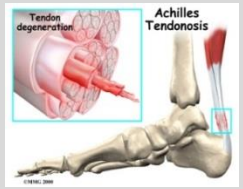		
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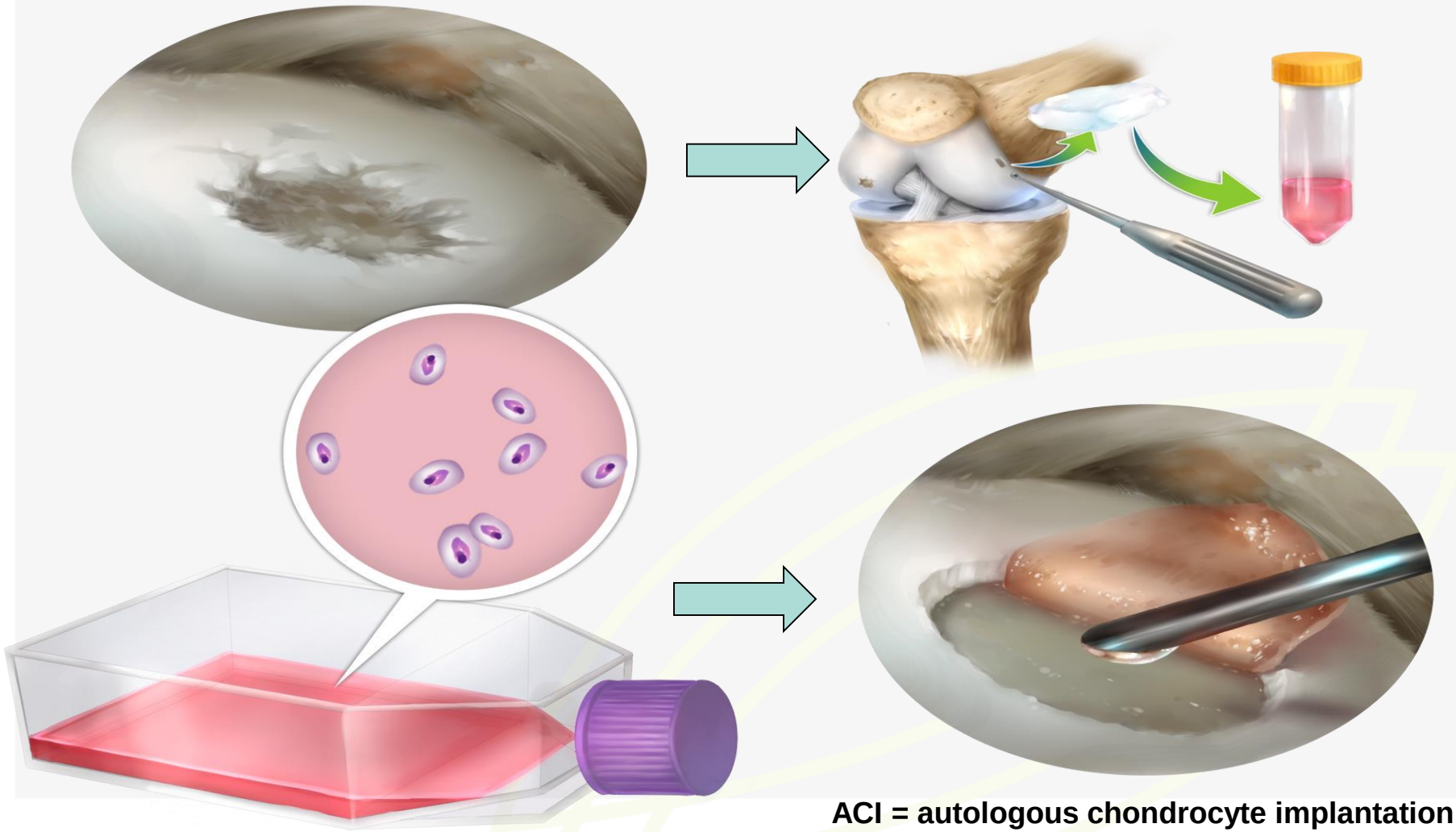
Ortho-ACI™- cartilage regeneration

Orthocell developed a new process called Ortho-ACI™ - the 3rd generation ACI

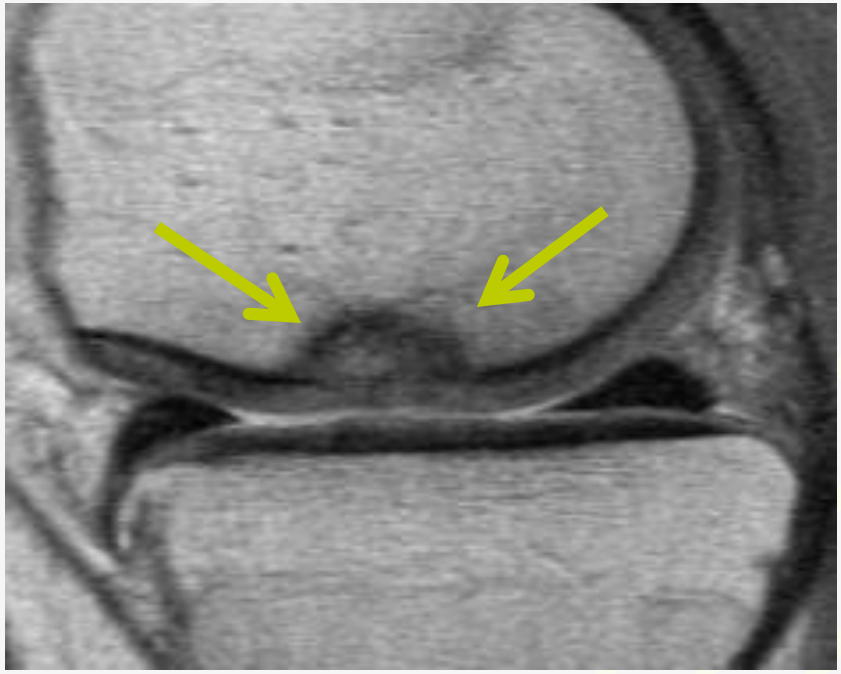


ACI = autologous chondrocyte implantation

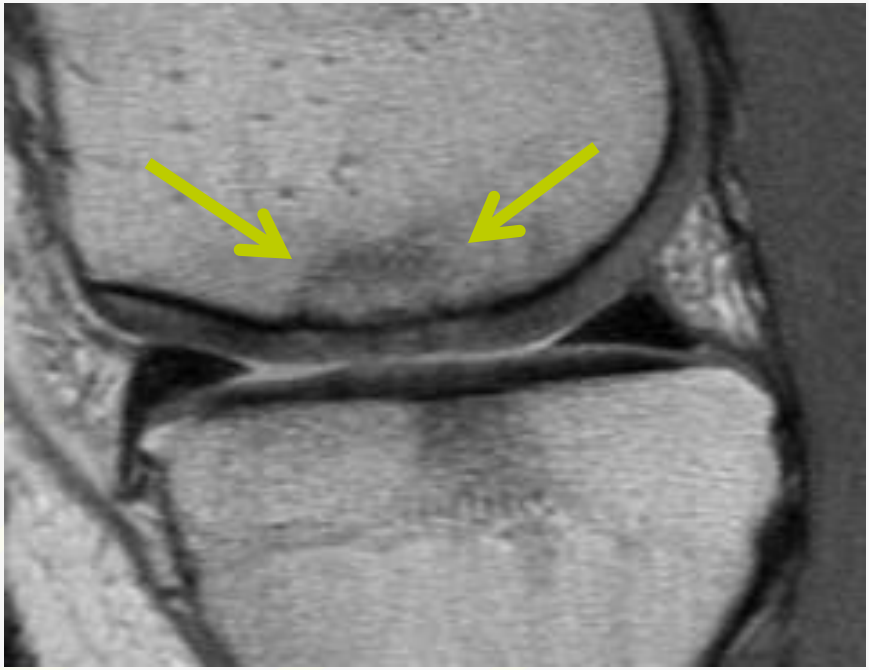
Restores cartilage anatomy

Orthocell founders were instrumental in developing the first generation ACI and gaining TGA approval for the first cell therapy to repair damaged cartilage

Damaged Articular Cartilage



9 months post ACI



Ortho-ACI™ - Marketing Strategy

- **Ramp up product sales**
  - already revenue generating in Australia – 250+ patients treated
  - existing strong relationships with key prescribers – orthopaedic surgeons
  - direct sales capacity expansion in NSW and Victoria planned
  - pursue reimbursement application in Australia post ARTG registration
- **Explore further licensing deals**
  - license deal with publicly listed Chinese company *Grandhope Biotech Co Ltd* in 2013
  - Japanese regulatory changes provide opportunity
- **Maintain regulatory license**
  - license to manufacture from TGA in place – additional approvals lodged for ARTG registration

TGA approved cGMP facility

- Two ISO 14644-1 clean rooms for human tissue processing
- Manufacturing licence issued by TGA which is subject to annual audit
- Quality system regularly reviewed and updated and tech transfer achieved for Chinese licensee
- Facility supports commercial manufacturing of Ortho-ATI™ and Ortho-ACI™ and will support early stage commercialisation of CelGro™
- Expansion footprint secured within building envelope for future clean room construction if required

Strong IP Portfolio

Patent Family	Description	Status
Tenocyte cell culturing method	Method for collecting, preparing and culturing tendon cells (tenocytes) for Ortho-ATI™ therapy	Granted – *Australia, USA, NZ, Singapore* Pending – *Canada, China, Europe*
Tenocyte containing bioscaffolds	Method for preparing bioscaffolds useful in the repair of tears	Granted – *China, NZ, Singapore* Pending – *Australia, USA, Europe, Canada*
A collagen scaffold for cell growth and a method for producing same	CelGro™ method manufacture	Granted – *NZ, Singapore* Pending – *Australia, USA, Canada, China*
Method of tissue repair	Ortho-ACI™ repair method	Granted – *Australia, NZ* Pending – *Canada, Europe, USA, Singapore, China*
Method for producing a collagen membrane and uses thereof	CelGro™ method of manufacture	Pending – *International, USA*

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Thank you

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Paul Anderson
Managing Director