

## Orthocell presents at Stem Cell Meeting on the Mesa

- Orthocell presents at leading international stem cell conference, Stem Cell Meeting on the Mesa in La Jolla California
- Managing Director Paul Anderson presents at key Australian biotechnology conference, Ausbiotech
- Orthocell therapy Ortho-ATI™ presented at global meeting of sports physicians in Barcelona

**Perth, Australia; 8 October 2015:** Regenerative medicine company Orthocell Limited is pleased to announce that the company will be undertaking a number of presentations this week at industry symposia and a global meeting of sports physicians.

Orthocell will be presenting previously announced positive data around its Ortho-ATI™ treatment for degenerate tendon and pipeline opportunities at the Partnering Forum at a leading international stem cell conference in the US. The Partnering Forum is part of the Stem Cell Meeting on the Mesa, being held October 7-9 in La Jolla, California.

The Company's presentation, which is attached, will be webcast via the Stem Cell on the Mesa website and can be found by following the link <http://stemcellmeetingonthemesa.com/webcast/>.

The 2015 Stem Cell Meeting on the Mesa is a regenerative medicine conference that brings together some of the world's leading companies and their top executives and industry decision makers to discuss research and translational approaches for difficult to treat conditions and diseases. The meeting is co-hosted by the Alliance for Regenerative Medicine (ARM), the California Institute for Regenerative Medicine (CIRM), and the Sanford Consortium for Regenerative Medicine and is a three-day stem cell conference featuring a two-day Partnering Forum, a Public Forum Lecture and a full-day scientific symposium.

Meanwhile, Orthocell Managing Director Paul Anderson will be presenting and taking part in a panel discussion at Australia's leading biotechnology conference, Ausbiotech 2015 in Melbourne. The conference is being held from October 7-9.

Mr Anderson will be taking part in a regenerative medicine symposium on October 8 in a session titled "Challenges to Commercialisation and translation of cellular therapies".

Mr Anderson said Orthocell's attendance at key conferences around the world reflected the growing interest in regenerative medicine therapies such as Orthocell's and the improvements they can make to people's lives.

"We welcome every opportunity to share the successes we're showing with our treatments and the improvements in people's lives," he said.

“As the population around the world ages, there will be a growing need for effective therapies that treat the wear and tear on our bodies as we age.”

Finally, leading Australian sports physician Dr Arjun Rao will also be presenting Orthocell’s previously announced positive Ortho-ATI™ results at the 7<sup>th</sup> Muscletech Network Workshop and 4<sup>th</sup> Congress of the European College of the Sport and Exercise Physicians in Barcelona, Spain, on October 9.

Dr Rao, who is a fellow of the Australasian College of Sports Physicians, will also discuss patient outcomes of his use of Ortho-ATI™.

**For more information, please contact:**

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**About Orthocell Limited**

Orthocell is a commercial-stage, regenerative medicine company focused on regenerating mobility for patients and our ageing population by developing products for a variety of tendon, cartilage and soft tissue injuries. Orthocell’s portfolio of products include TGA-approved stem 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.



# Investor Presentation

September 2015

ASX: OCC



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# Company Overview



**Orthocell Ltd is a regenerative medicine company** developing cellular therapies and collagen scaffolds for the treatment of human tendons, ligaments and soft tissue defects



- Founded in 2006, headquartered in Australia, ASX listed August 2014
- Marketed products in Australia, Singapore, Hong Kong, New Zealand, with US clinical program advancing
- Unique cell therapy and regenerative medicine products:
  - **Ortho-ATI™** - world's only stem cell therapy to regenerate tendons and ligaments
  - **Celgro™** - significantly differentiated collagen scaffolds for soft tissue reconstruction and repair
  - **Ortho-ACI™** - next generation cartilage repair
- Additional commercial stage products in cartilage and pipeline products in laboratory grown tendon and growth factors

# Corporate Overview



## Corporate

ASX	OCC
Share Price	AU\$0.67 (@ 17 Sep 2015)
Ordinary Shares on issue	82.5 million
Market Cap	AU\$55 million
Options outstanding	5,912,500 (ex @ \$0.50) 3,520,000 (ex @ \$0.62)
Cash at bank	AU\$4.7 million (@ 30 Jun 2015)

## Team

CEO	Paul Anderson	<ul style="list-style-type: none"><li>• Verigen</li><li>• Genzyme</li><li>• Biomet</li></ul>
CSO	Prof Ming Hao Zheng	<ul style="list-style-type: none"><li>• Verigen</li><li>• Genzyme</li><li>• UWA</li></ul>
Executive Chairman	Dr Stewart Washer	<ul style="list-style-type: none"><li>• Cynata</li><li>• Minomic</li></ul>
Director	Matt Callahan	<ul style="list-style-type: none"><li>• iCeutica</li><li>• Glycan Bio</li><li>• Dimerix</li></ul>
Director	Prof Lars Lidgren	<ul style="list-style-type: none"><li>• UN Bone and Joint Chair</li><li>• Biomet</li><li>• Uni Lund</li></ul>

## Shareholding Structure

Shareholders **2,700** Directors & Management **33%** **63.7%** Top 20

# Ortho-ATI™ – Autologous Tenocyte Implantation



**Ortho-ATI™ is a stem cell therapy to regenerate tendons and ligaments which:**

- uses each patient's own stem cells to regenerate tendon tissue
- enables healing of tendons, reduces pain and increases strength
- greatly improves the patient's mobility and quality of life
- multiple tendon applications

**Ortho-ATI™ is a two stage minimally invasive, walk-in, walk-out process:**

- Biopsy procedure and tenocyte cultivation
- Cell implantation

- 4-5 week end to end process
- early systematic relief, followed by structural and functional improvements

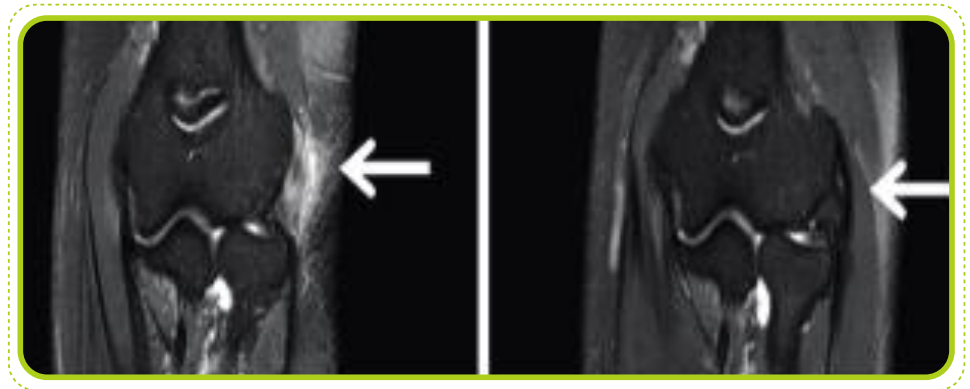
## Common Sites for Ortho-ATI™



# Positioning Ortho-ATI™



Ortho-ATI™ is positioned as the preferred treatment for the repair and regeneration of damaged/injured tendons:



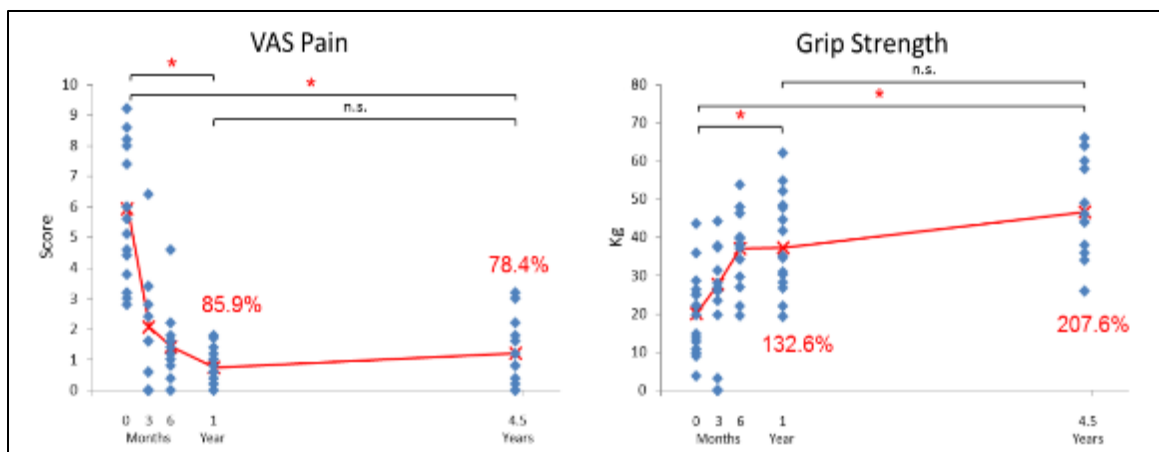
- ✓ **Directly addresses** the underlying pathology of tendinopathy (disease modifying)
- ✓ **Long term data** demonstrating durability and effectiveness in recalcitrant patients:
  - **Tennis Elbow** – structurally repaired tendon tissue, 203% improvement grip strength at (3-5 yrs)
  - **Gluteal Tendinopathy** – clinical improvements at 3 months, maintained to 24 months
- ✓ **Over 300 patients** treated to date. Demonstrated pathway to market
- ✓ **Non operative** procedure with high cost-benefit outcomes
- ✓ **Market leading** world first tendon regeneration treatment

# Ortho-ATI™ clinical data



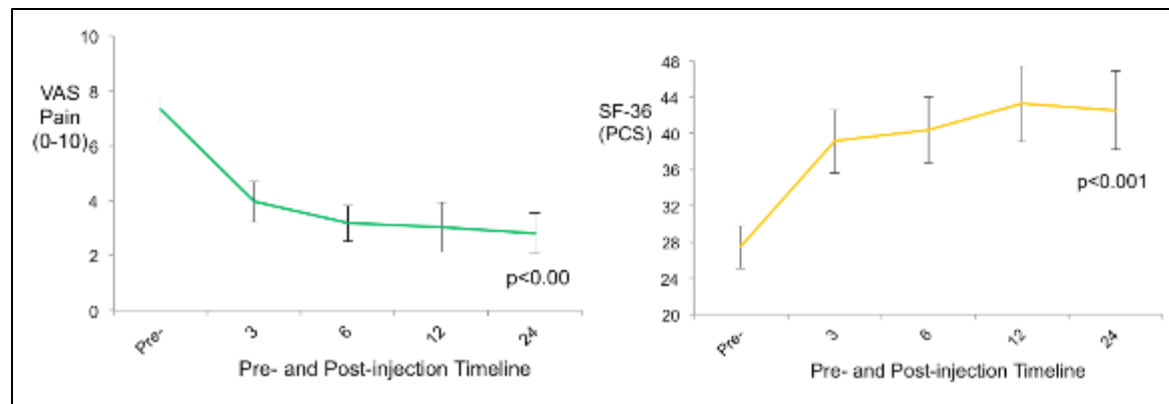
## Ortho-ATI™ tennis elbow study:

- 20 patients that had failed all other treatments, with average 31 month symptoms on
- Patients improved significantly with 1 patient proceeding to surgery
- Data to 4.5 years recently published in *American Journal Sports Medicine*



## Ortho-ATI™ gluteal tendon study:

- 12 patients with gluteal tendinopathy – no remaining treatment options average duration of symptoms of 33 months
- Significant clinical improvement in pain and function scores at 24 months
- Data submitted for publication



# Global expansion of Ortho-ATI™

## Australian approval and marketing of Ortho-ATI™ de-risks global expansion:

- 300 patients treated in Australia and parts of Asia
- multiple tendons treated with no reported serious AE's
- sales tools and market entry strategy honed in pilot market

## Bringing Ortho-ATI™ to the world's largest markets:

- IND being prepared for US Phase 2 tennis elbow study
- partnering discussions ongoing with US and EU potential partners
- initial discussions in Japan underway to leverage abridged approval process

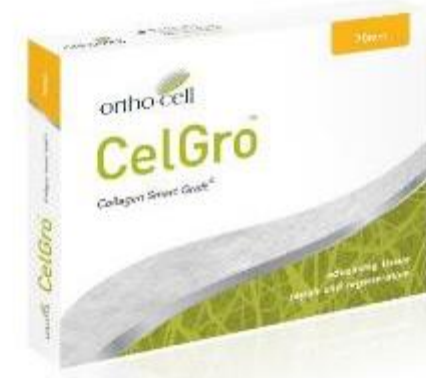


# Collagen Scaffold Platform CelGro™



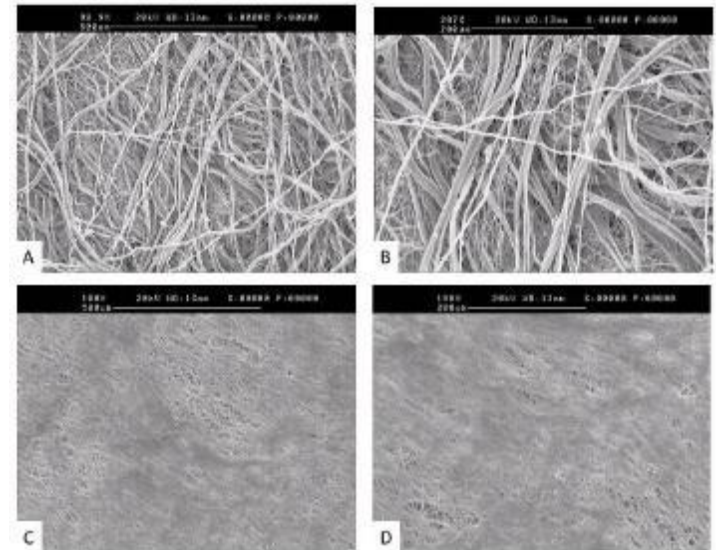
## CelGro™ is a superior soft tissue regeneration technology:

- natural source with consistent resorption
- pure with no foreign DNA
- high mechanical strength and pliability
- superior cell compatibility



## Multiple applications:

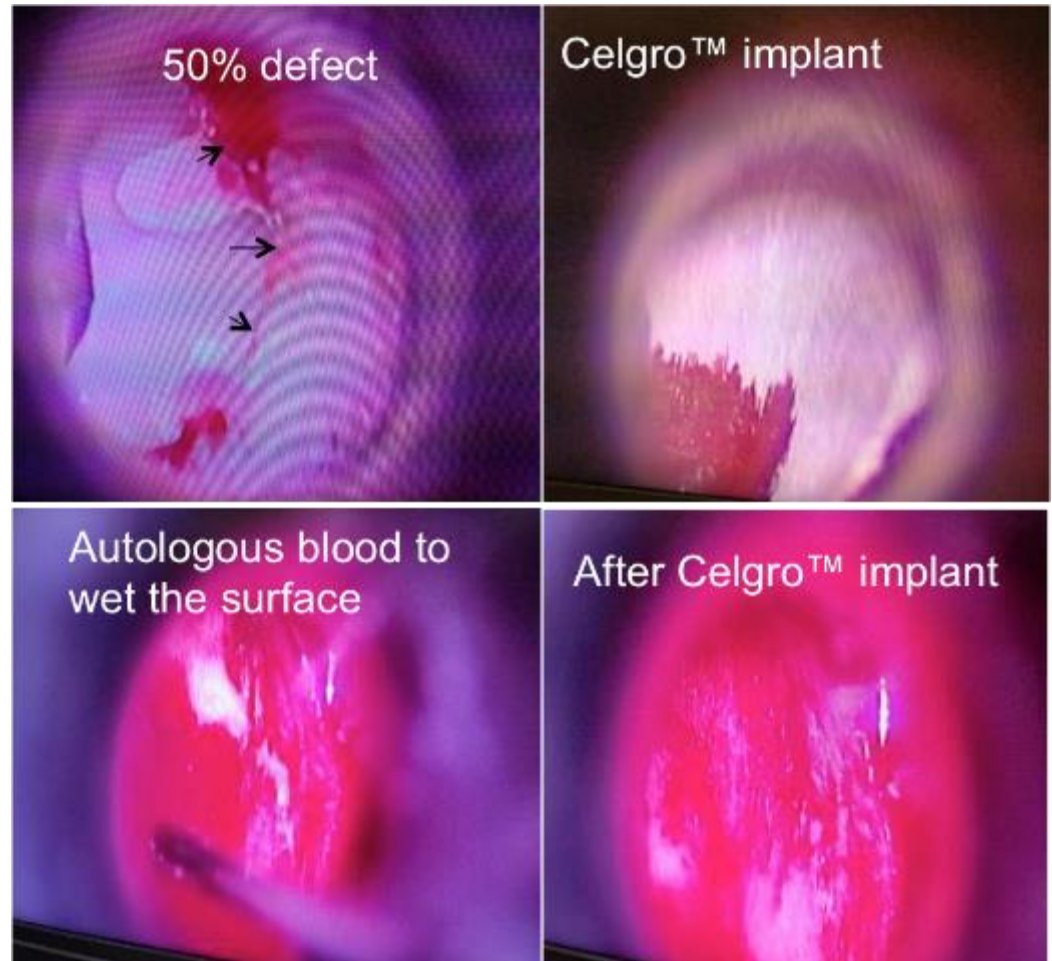
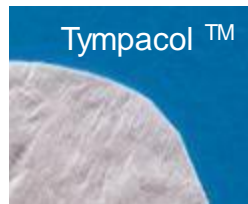
- tendon augmentation and repair
- dental
- bone repair and regeneration
- gynaecological and urological soft tissue repair
- general surgical soft tissue reconstruction
- ENT tympanic membrane
- Nerve repair



# Celgro™ clinical data – ear drum

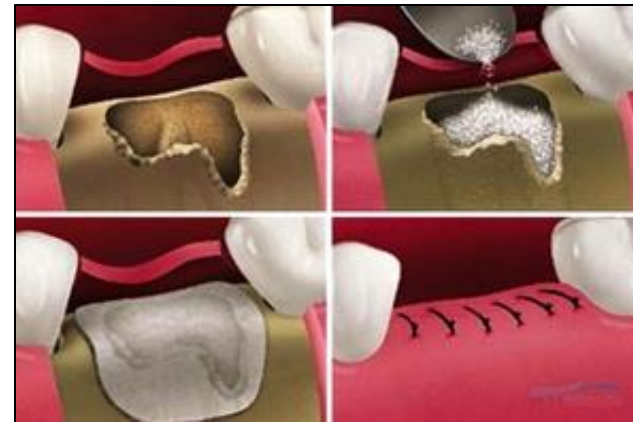
## Celgro™ ear drum (tympanic membrane) repair feasibility study:

- 7 patients with chronically ruptured ear drums, normal surgical repair failed
- Extremely thin (80 micron) Celgro™ scaffold utilized to replace ear drum
- Pilot complete – preparing for efficacy study
- Human safety data incorporated in Celgro™ European CE Mark filing for 2015



## Celgro™ dental soft tissue repair study:

- 30 patient open label study requiring bone grafts to enable dental implants
- Dentacol™ utilized for guided bone regeneration and to stop soft tissue ingrowth
- Study underway with pleasing initial results
- Human safety data incorporated in European CE Mark filing for 2015



# Next generation pipeline

## Strong product pipeline:

### Celgro

- collagen powder for bone void fillers
- guided nerve regeneration
- braided ligament and ACL replacement

### Lab Grown Tendons

- laboratory manufactured human tendon
- replacement tendons for hands and other applications

### Growth Factors

- tissue specific growth factor 'Cell Factory'
- off the shelf growth factors - bone, cartilage and tendon



These pipeline products and concepts are early stage opportunities that require further research and development prior commercialisation

# Positioned for growth



**Approved treatments with strong clinical evidence**

First tendon and ligament regeneration product in a major market with 300 patients treated in a range of tendon applications



**Significant unmet medical need**

Market for musculoskeletal conditions in US, EU and Japan targeted by Orthocell therapies exceeds \$7 B per annum



**TGA approved manufacturing facility**

Manufacturing facility in Australia already approved for commercial production and SOP's transferable to support clinical development in US/EU/JP



**Next product in late stage development**

Celgro™ planned for registration application in 2015



**Global approvals and expansion underway**

US clinical program advancing with IND in preparation and opportunity for abridged approvals in Japan



**Team with track record**

Team secured Australia's first cell therapy approval and Board has significant M&A and capital markets experience