

Investor presentation Finance News Network

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Regenerative medicine





What is regenerative medicine?

A new field of medicine seeking to repair injured or diseased tissue using the body's own regenerative capabilities

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



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

What is Orthocell's position in this space?

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

Board of directors



Experienced Board with prior success commercialising regenerative medicine



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
 Australia
- Extensive experience in commercialising emerging technologies



Matthew Callahan Board Member

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



Professor Lars Lidgren Board Member

- World leading innovator in the orthopaedic space
- Entrepreneur and founder of multiple biotech companies (Scandimed, Bone Support, AMeC and 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

Innovative products



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



Cell therapy to regenerate

damaged tendon tissue



- Approved for sale in Europe (CE Mark)¹
- 26% superior clinical performance¹
- **Platform technology** multiple indications
- Optimised manufacturing capabilities
- Static market that lacks of innovation
- Global partnering opportunities
- First in class cell therapy for tendon repair
- Significant unmet clinical need
- Global partnering major US collaboration partner
- De-risked with +500 patients treated to date
- Licence to manufacture and treat patients in Australia, Singapore and Hong Kong (TGA)
- US regulatory focus process underway

Total addressable market is estimated to be in excess of US\$10bn p.a.²

- 1. CelGro® for dental bone and soft tissue repair
- 2. Addressable markets include US, Japanese, European and Australian markets, 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®

A unique collagen medical device that augments tissue repair and regeneration



CelGro[®]: initial focus in bone regeneration



Orthocell's initial focus is on driving sales of CelGro® in the lucrative EU market

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

Illustrative example



Defect Site - insufficient bone volume available



Bone Graft - defect site filled



Apply CelGro[®] - placed over defect site



Implant Crown - tissue stitched over CelGro[®] and crown secured

1. US, Japanese, European and Australian markets based on ~1.5m procedures per year

CelGro[®]: bone regeneration market opportunity

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. 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

2. US, Japanese, European and Australian markets based on ~1.5m procedures per year



Superior clinical performance



CelGro[®]: accelerating sales in dental bone



With optimised and scalable manufacturing in place, regulatory approval achieved and KOL's appointed, Orthocell is well placed to execute on its marketing and sales strategy

Educating clinicians

Roll out KOL-lead clinician training program. Support distributors develop customer base.

Access new markets

Entry to new, high value EU markets (Spain and Germany). Access domestic market through the Special Access Scheme.



Marketing data

Generate supplementary marketing data through *Centres of Excellence* supporting product performance.

Drive awareness

Sponsorship of key dental bone repair congresses. Commence targeted advertising campaign.

CelGro[®] strategic focus



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



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.



CelGro[®]- nerve repair market opportunity

Very favourable market dynamics:



Millions of people suffer from peripheral nerve injury as a result of motor-vehicle, sporting or workrelated incidents



Existing products have inferior functionality and handling characteristics



Strong demand from orthopaedic surgeons



- Market leader generates \$US80m p.a. in US alone
- Significant addressable market US\$1.1bn

CelGro[®] is designed for suture-less reconnection of severed or damaged nerves, guiding nerve regeneration and accelerating the healing process



"CelGro® is easier to use and performs better for its intended purpose. It is not rigid – it facilitates tensionless repair, increases the strength of the repair, and creates a bioactive chamber for healing." - Dr Alex O'Beirne, Orthopaedic nerve specialist and CelGro® trial Principal Investigator

CelGro®- revolutionising nerve repair



Patients regain increased sensation and muscle function in affected limbs following CelGro[®] nerve regeneration treatment

Trial participant nerve injuries:

- Result in complete paralysis or impaired use of hand and upper limbs
- Significant pain
- Unable to perform basic activities of daily living (ie eating, bathing, dressing and toileting), play sport and/or work

First patients complete nerve regeneration trial:

- Regain sensation and function in affected limbs
 - 83% improvement in muscle power
 - Commenced return to work, sport and activities of daily living

After my football injury, I had no feeling in my right shoulder. I couldn't pick up my kids, swim, or play football. ... I'm living a normal life now. I can pick up my kids and I even swam a duo to Rottnest! I might even be able to play footy again next year, something that I thought would never happen." - **Daniel Hunt, trial participant.**



Next steps



Regenerative medicine case study: PolyNovo



Orthocell is well positioned to deliver significant shareholder upside in the near term

ortho cell Rerating based on:

- CelGro[®] gaining traction in key markets
- Achieving US approval for CelGro[®]
- Potential to address multiple indications, in significant markets with multiple products
- Ortho-ATI[®] commercialisation (research collaboration with a major US partner)
- Global partnering opportunities

Strong share price movement in the months following first sales in a large, attractive international market



Corporate overview



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

0.40 2,000 1,600 0.30 1,200 0.20 800 0.10 400 Nov-18 Mar-18 May-18 Jul-18 Sep-18 Jan-19 Mar-19 Volume traded (RHS) OCC (LHS)

Share price performance

Trading information

Share price (06-May-19)	A\$0.1150
Shares on issue ¹	120.7m
Market capitalisation	~A\$14m
Cash (as at 31-Mch-19) ²	A\$3.2m
Debt (as at 31-Dec-18)	-
Enterprise value	A\$10.8m

Top shareholders (as at May-19)

Stone Ridge Ventures – Associated with non-executive director	7.89%
Ming Hao Zheng – CSO and founder	5.9%
Paul Anderson – Managing director	5.3%
Qi Xiao Zhou – Non-executive director	5.0%
Mr Jia Xun Xu – Former director	4.3%

1. Excludes 12.1m unquoted warrants with exercise price \$0.58, expiry 19-Nov-2020 and 16.0m unquoted options with exercise prices ranging from \$0.51-\$0.65 and expiry dates between Feb-2019 and Jun-2020

2. Excludes R&D tax incentive refund of A\$2.5m received in October 2019



Upcoming catalysts

CelGro® - Dental

Roll out European education program	Ongoing
Commence European advertising campaign	2Q CY2019
Italy and UK sales growth	3Q CY2019
Spain and Germany market entry	3Q CY2019
Australian market authorisation	4Q CY2019
US market authorisation	1Q CY2020

CelGro[®] - Orthopaedic	
Tendon repair clinical data	2Q CY2019
CE Mark (EU) submission	3Q CY2019
TGA (AUS) submission	3Q CY2019

Ortho-ATI ®	
Investigation New Drug submission FDA	2Q CY2019
Complete J&J study recruitment	2Q CY2019

Strategic partnership discussions ongoing for all products



Key investment highlights



Significant upside

Significant market interest Addressable markets worth >US\$10bn p.a.



De-risked product portfolio

Substantial clinical data CE Mark (EU) achieved for CelGro¹



Validated manufacturing process GMP-certified and TGA-licensed manufacturing capabilities



Credentialed and highly aligned leadership *Proven track record in commercialising cell therapy products*

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