Restoring function to paralysed limbs

Bell Potter Healthcare Conference
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Key Investment Highlights

Orthocell is a regenerative medicine company delivering breakthrough products for the treatment of serious musculoskeletal disorders.

Advanced product portfolio with significant clinical evidence	GMP-certified and TGA-licensed manufacturing capabilities	Global patent portfolio	Credentialed and highly aligned leadership	Near-term milestones
Leading de-risked portfolio of regenerative medicine products that have shown in clinical studies and real world evidence to return patients to work, activities of daily living and elite sport pain-free.	Orthocell's Good Manufacturing Practice certified and Therapeutic Goods Administration licensed manufacturing facility underpin the Company's competitive advantage and can be readily scaled to meet market demand.	Regenerative medicine manufacturing technologies, products and treatment processes patent protected in all major jurisdictions including US, EU, China, Japan and AUS.	Credentialed and highly aligned leadership Orthocell is led by an experienced Board and management team with a successful track record of developing and commercialising novel healthcare and technology products.	Multiple near-term catalysts including US and AUS approvals of CelGro® in the near term and completion of Ortho-ATI™ study in collaboration with DePuy Synthes Products, Inc., part of the Johnson & Johnson Medical Device Companies.

$ Well-funded with $18.9m cash as at September 30, 2020

About Orthocell Ltd

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

CelGro®

Collagen medical device

- **Designed to augment surgical repair of soft tissue.**
- **Represents a breakthrough** in soft tissue reconstruction.
- **Multiple applications** in nerve, tendon, and bone repair.
- **Demonstrated superior clinical performance** when compared to the current market leading product.
- **Initial EU approval achieved.**

Ortho-ATI®

Cell therapy for tendon regeneration

- **Injectable clinical stage cellular therapy** for treatment of chronic tendon injuries.
- **Multiple tendon sites** including shoulder, elbow, hip, hamstring and achilles.
- **Addressing a significant unmet clinical need** for a safe, effective and non-surgical solution.
- **First injectable cellular therapy in orthopaedics** for tendon regeneration.

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Significant market opportunity

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

CelGro®– – – – – – – – – Ortho-ATI® – – – – – – – Total addressable market

>US$10bn

>US$7.7bn >US$17 billion p.a.

Driven by rising rate of musculoskeletal disorders and demand for efficient and cost-effective treatments.

1. 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

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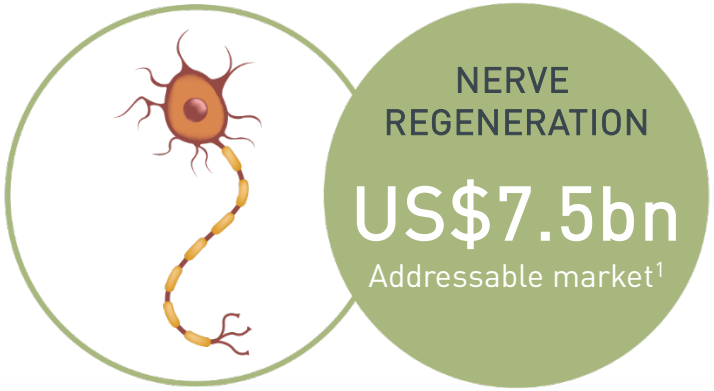
CelGro®

A unique collagen medical device that augments tissue repair and regeneration

CelGro®: strategic focus

Orthocell is focused on the development and commercialisation of the nerve, tendon and bone applications.

CelGro® has significant global commercial potential in its existing addressable markets as well as much wider applications in general surgical and soft tissue reconstructive applications.



NERVE REGENERATION

US$7.5bn

Addressable market[1]

TENDON AND LIGAMENTS

US$1.4bn

Addressable market[1]

BONE REGENERATION

US$1bn

Addressable market[1]

1. US, Japanese, European and Australian markets.

Analysis of addressable markets excludes the following CelGro® pipeline products including articular cartilage repair, ACL ligament replacement & general surgery.

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CelGro® Nerve Regeneration

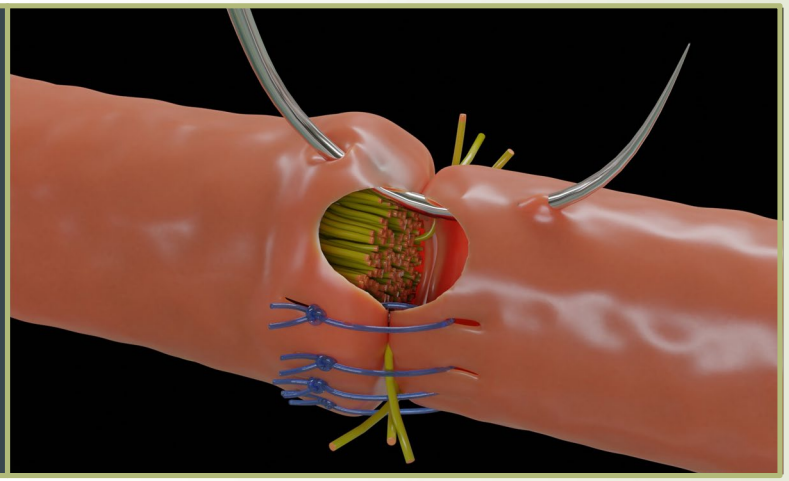
Revolutionising nerve repair

Traditional repair outcomes are suboptimal

Using traditional repair methods for crushed/severed nerves can be ineffective and unpredictable in restoring function to affected limbs.

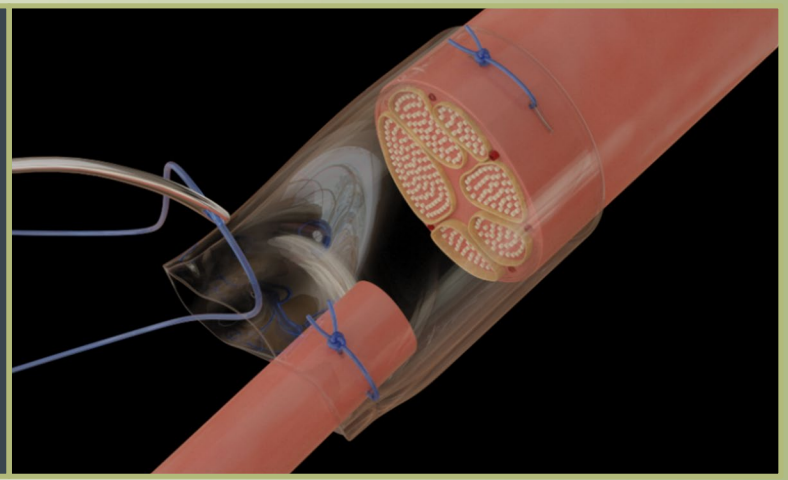
Direct suture

Tension can result in buckling and misdirection of regeneration nerve fibres



Rigid hollow tube

Rigid tubes are limited in use and efficacy and can result in a 34-57% failure rate[1]



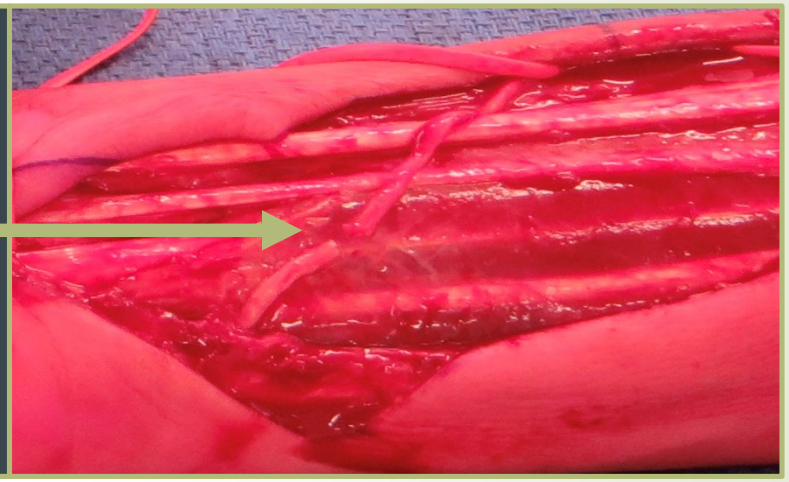
Strong demand for a medical device that enables surgeons to perform complex surgical repairs efficiently with better results

1. Weber, et al. A randomized prospective study of polyglycolic acid conduits for digital nerve reconstruction in humans. PlastReconstrSurg. 2000; 106(5): 1036-1045.

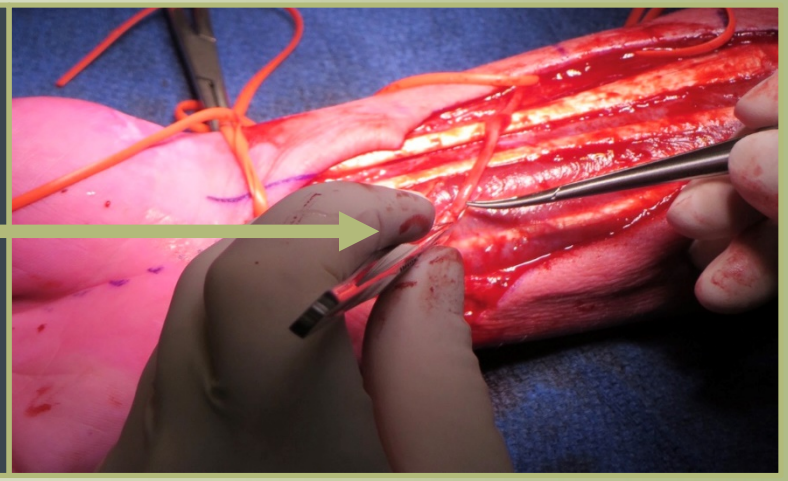
CelGro®: nerve transfer surgery

CelGro® is a versatile medical device that can be used to repair, protect and cap nerve injuries to return function to impaired or paralysed muscles.

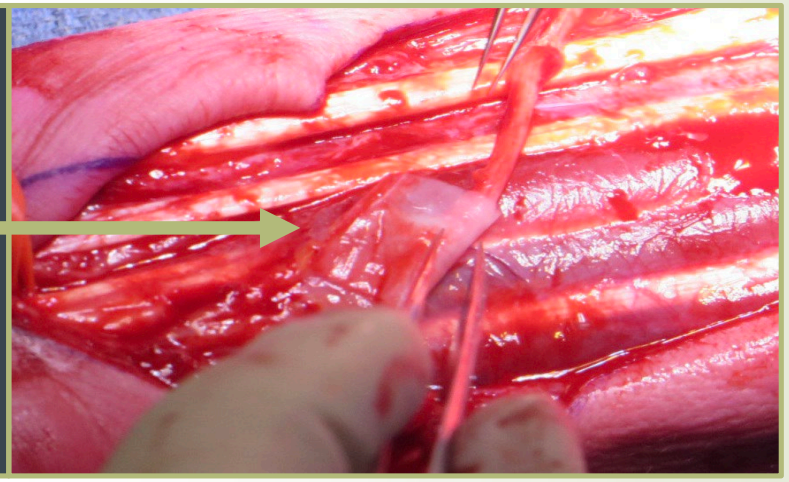
1
Transferring superficial radial to ulnar nerve



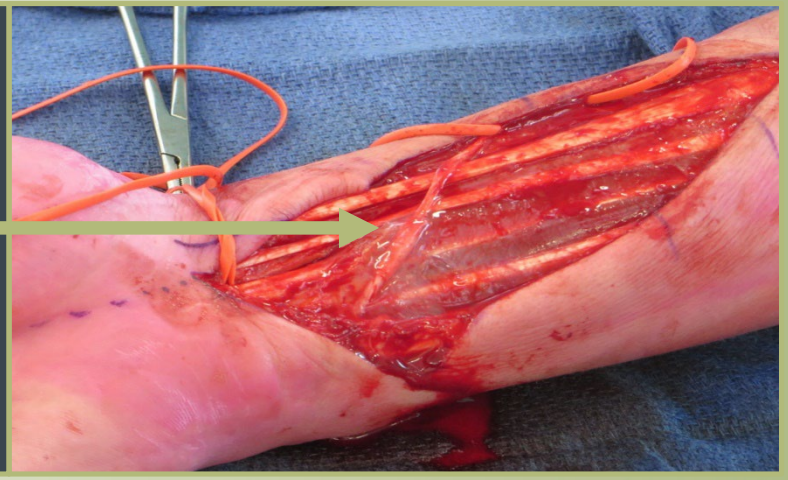
2
Placing a stay suture to oppose nerve ends



3
Wrapping CelGro® around nerve ends to create a customised conduit



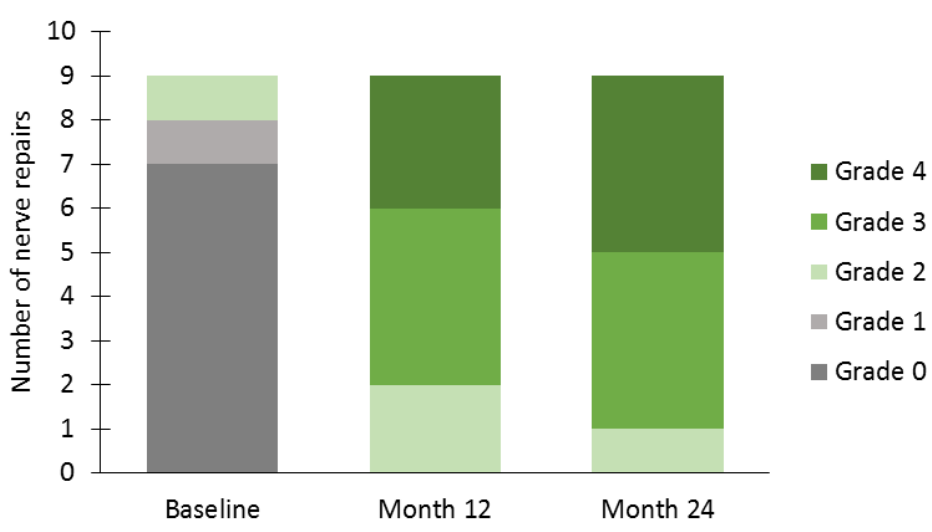
4
CelGro® guides and supports nerve repair



CelGro®: compelling long term clinical results

Quadriplegic patients regained voluntary muscle movement within 12 months

Figure 1 – Recovery of Muscle Power in Patients with Quadriplegia



Grade 3 and 4 – voluntary movement with improved strength and range of motion. **Maximum level of recovery expected.**

Grade 2 – voluntary movement restored, limited strength and range of movement.

Grade 0 or 1 – no voluntary movement.

- Quadriplegic patients regain independence - brushing teeth, drinking from a cup, and transferring into and out of a wheelchair without assistance
- Best case clinical outcome (MRC Grade 3 or 4) increased from 7 of 9 (78%) nerve repairs at12 months post treatment to 8 of 9 (89%) repairs at 24 months

Leading Australian orthopaedic nerve specialist and clinical trial lead, Dr Alex O'Beirne, said *"Using CelGro® has improved the success rate and efficiency of the surgery. Seeing patients regain enough independence, so that they can be involved in family life and return to work, is very rewarding."*

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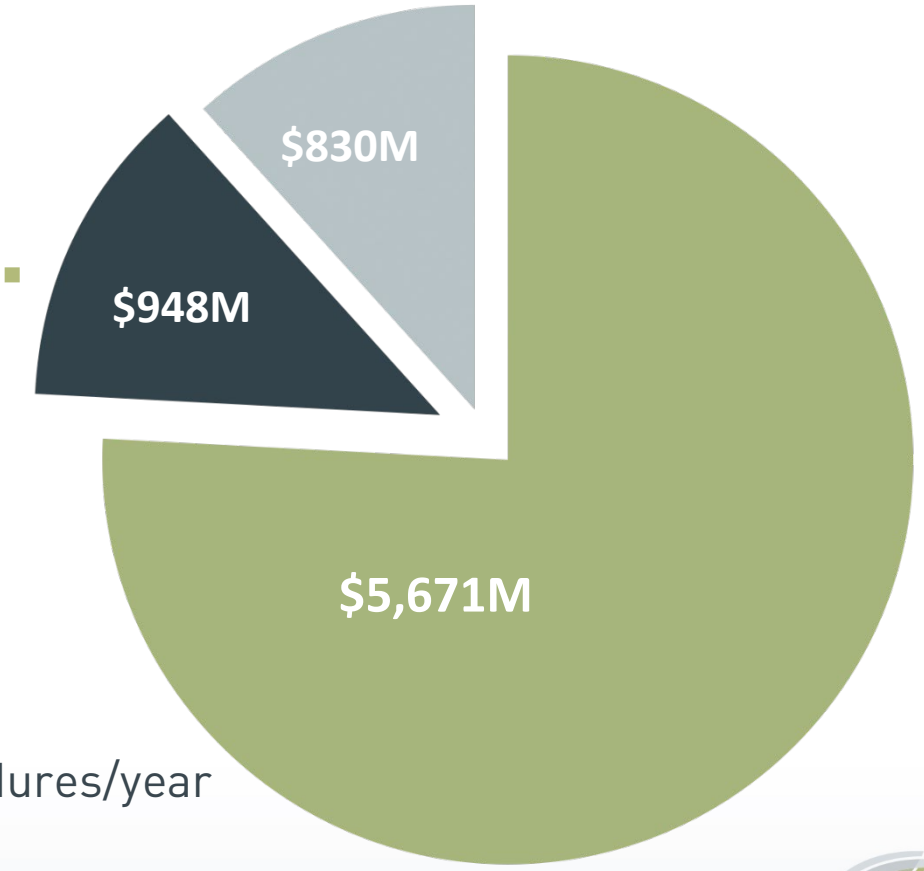
CelGro®: nerve repair market opportunity

CelGro®'s addressable market in peripheral nerve repair is estimated to be worth more than

>US$7.5 billion per year.



Global potential annual procedural estimates[1]:

- > CONNECT: severed nerve repair, >2,000,000 procedures/year
- > PROTECT: carpal and cubital tunnel revisions, >350,000 procedures/year
- > CAP: amputations, >300,000 procedures/years

1. Addressable markets include US, Japanese, European and Australian markets . Referenced papers were used to derive specific assumptions in the procedure potential estimates. Papers used include both U.S. and OUS databases and studies.

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Pathway to US market

With the safety and efficacy of the CelGro® nerve repair product established, Orthocell is focused on executing its regulatory program to gain approval in the US.

US 510(k) Study Purpose	To support an evaluation of substantial equivalence to an approved nerve repair device, meeting the requirements of the US 510(k) predicate product regulatory pathway.
Study Design	The study will involve the treatment of severed sciatic nerves in approximately seventy six (76) rats in three (3) study groups (control, CelGro® and comparator) with outcome measures recorded at four, eight and twenty weeks post treatment. The key outcome measures include the performance of CelGro® in facilitating high quality nerve regeneration and restoration of motor and sensory function.
Collaboration	Conducted in collaboration with University of Western Australia and Western Sydney.
Key Milestones	✔ US FDA pre-submission meeting ✔ Ethics approval ☐ Commence surgical procedures Q4 CY2020 ☐ Final data read out target Q4 CY2021

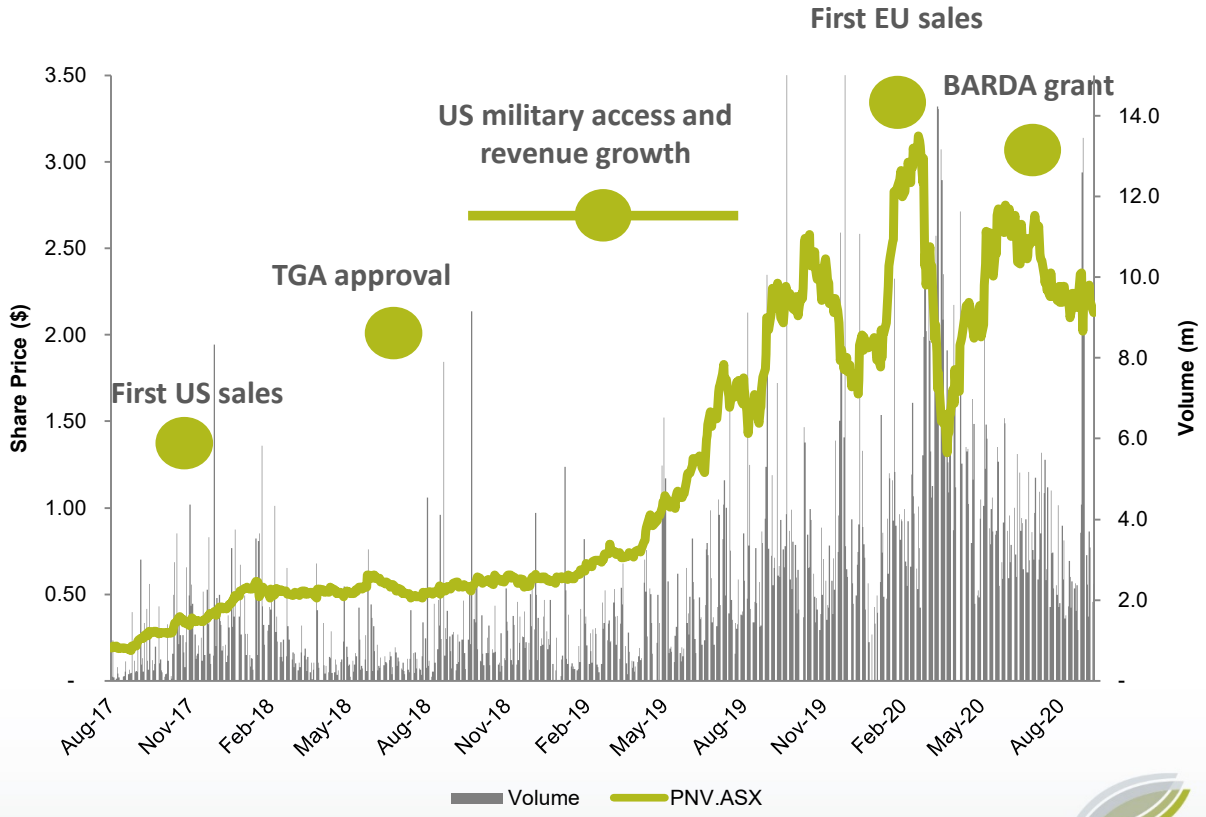
Near-term milestones

Regenerative medicine case study: PolyNovo®

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

Value Drivers:

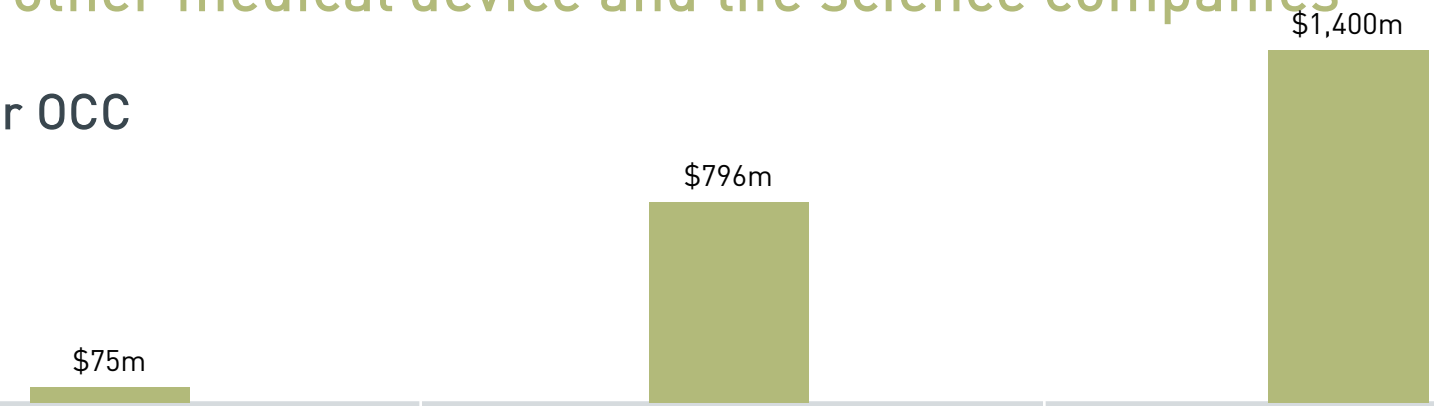
- US and AUS market authorisation
- Brand ambassadors and additional marketing data
- Gaining traction in key markets with distribution partners
- BARDA grants and military access



Valuation upside

Valuation comparison to other medical device and life science companies

Significant upside potential for OCC



Market Capitalisation	$75m	$796m	$1,400m
Company	ortho·cell	avita medical	PolyNovo®
Device	Autologous Injection and medical device	Autologous cell harvesting device	Synthetic scaffold device
Indication	Bone, tendon and nerve	Acute thermal burn wounds	Dermal wound repair
Stage	US Approval Pending	US Approved 2018	US Approved 2015

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Upcoming catalysts[1]

CelGro®: Dental

Australian market authorisation estimate	4Q CY2020
US market authorisation estimate	2Q CY2021

CelGro®: Nerve and Tendon

Clinical study data update (nerve)	4Q CY2020
Australian market authorisation estimate (nerve)	CY2021
Commence FDA (US) regulatory study (nerve)	4Q CY2020
TGA (AUS) submission estimate (tendon)	4Q CY2020

Ortho-ATI®

Investigation New Drug submission FDA (estimate)	1Q CY2021
Ortho-ATI v Corticosteroid (RCT) study complete	3Q CY2021
Ortho-ATI v Surgery (RCT) recruitment complete (estimate)	CY2021

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1. Timelines are an estimate only and may be subject to change due to matters not under the Company's control such as COVID-19 mitigation measures.

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