

A man and a woman are jogging on a paved path in a park. The man is on the left, wearing a light blue t-shirt and white shorts. The woman is on the right, wearing a grey long-sleeved shirt and purple leggings. They are both smiling and appear to be in good health. The background is a lush green park with many trees.

Investor Presentation

Bell Potter Healthcare Conference
November 2021

The logo for OrthoCell, featuring a stylized green and grey leaf-like shape above the text.

ortho·cell

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Key Investment Highlights

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

 <p>Advanced product portfolio with significant clinical evidence</p>	 <p>GMP-certified and TGA-licensed manufacturing capabilities</p>	 <p>Global patent portfolio</p>	 <p>Credentialed and highly aligned leadership</p>	 <p>Near-term milestones</p>
<p>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.</p>	<p>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.</p>	<p>Regenerative medicine manufacturing technologies, products and treatment processes patent protected in all major jurisdictions including US, EU, China, Japan and AUS.</p>	<p>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.</p>	<p>Multiple near-term catalysts including commercialisation of Striate+ into the US and advancing the development and approvals of breakthrough products in nerve and tendon regeneration.</p>

\$ Well-funded with \$14.6m cash as at September 30, 2021

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 US, EU and AUS approval achieved.**

Ortho-ATI[®]

Cell therapy for tendon regeneration



- **First 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.
- **Ortho-ATI v Corticosteroid (RCT) study results on track for Q4 CY2021**

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

US Strategic Focus

Advanced product portfolio with near term milestones and emerging pipeline

Product	Application	Clinical Development Phase	US Regulatory Phase			Upcoming Catalysts
			Design Trial	Implement Trial	Approved	
CelGro [®] Medical Device	Striate+ ¹					US market entry - engage marketing and distribution partner
	Remplir ²					US commercialisation strategy - finalise US regulatory/reimbursement study
	SMRT Rope (Ligament replacement)					Commence pre-clinical study - ACL repair
Ortho-ATI [™] Cell Therapy	Rotator cuff					Release RCT results - Ortho-ATI v corticosteroids
	Lateral epicondyle					Finish recruitment - Ortho-ATI v surgery

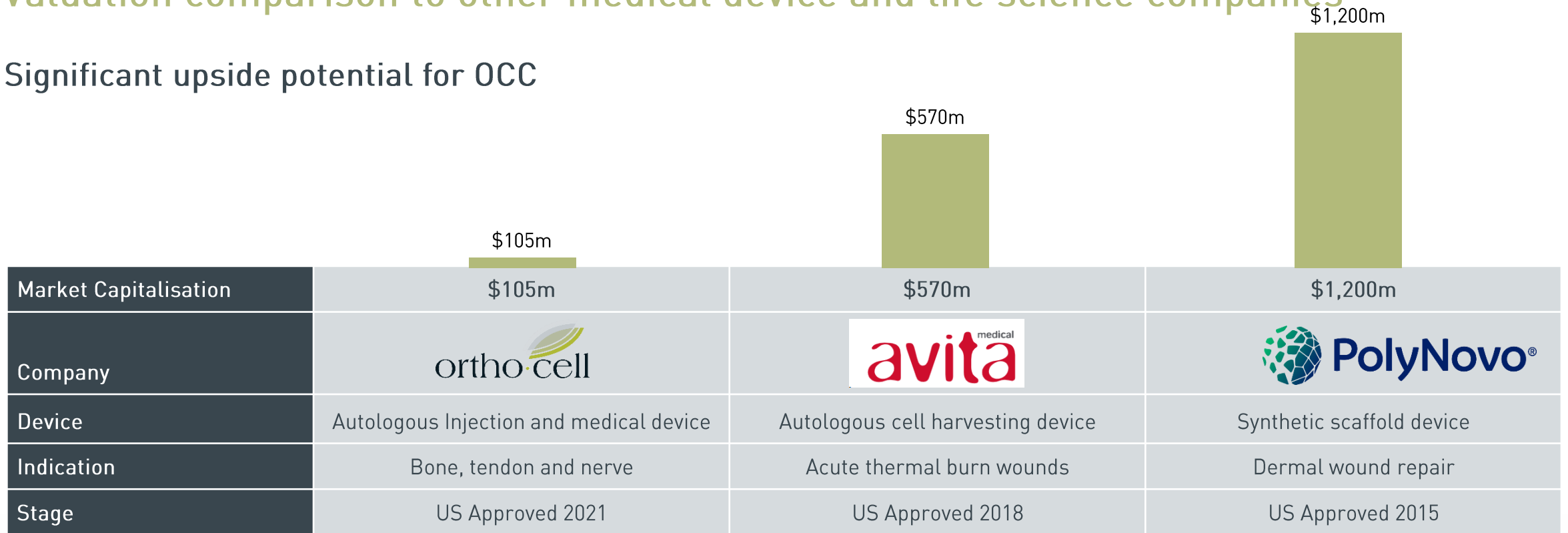
1. Approved in the US, AUS and EU

2. Application submitted for AUS approval

Valuation upside

Valuation comparison to other medical device and life science companies

Significant upside potential for OCC





Ortho-ATI®

Advanced cellular therapy to directly address the root cause of degenerate tendon injury

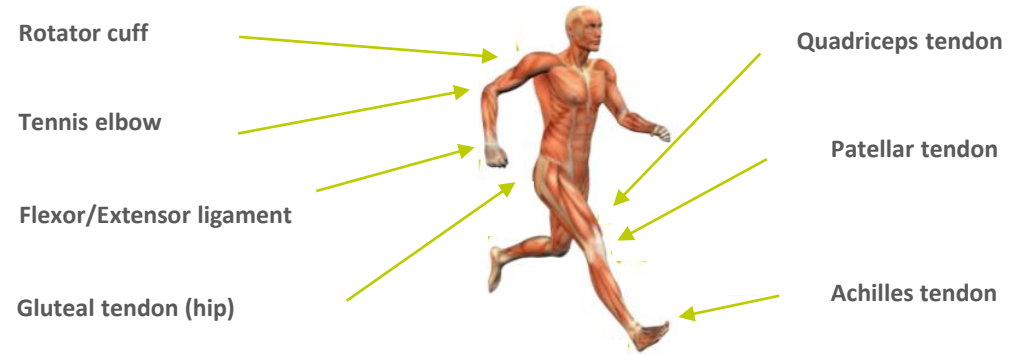
Chronic tendon injury: significant unmet clinical need

Chronic tendon injury is a common and painful disorder affecting millions of people every year with no effective, non-surgical treatments currently available

Significant unmet clinical need

- Millions of people suffer from chronic tendon injury every year
- Traditional repair outcomes suboptimal i.e. PRP, corticosteroids and surgery
- Chronic tendon injury significantly reduces the ability of patients to work, exercise, and perform routine daily activities

Multiple tendon injury sites



There are no 'non-surgical' treatments currently available to treat chronic tendon injury

Ortho-ATI[®]: a global clinical first

Injectable cell therapy that returns patients to the workplace, recreational activities and elite sport pain-free.

Ortho-ATI[®] is a novel treatment

- ✓ Breakthrough in regenerative medicine directly addressing the root cause of injury
- ✓ Replenishes degenerative tissue with healthy mature tendon cells, accelerating regeneration of tendon tissue
- ✓ Extensive clinical validation - over 700 patients treated with Ortho-ATI[™] to date
- ✓ Optimised manufacturing capabilities: GMP-certified and TGA-licensed facility¹ and PPI² release criteria in place

1. GMP: good manufacturing practices; TGA: Therapeutic Goods Administration
2. PPI: purity, potency and identity

Two stage, minimally invasive procedure



Ortho-ATI[®] : compelling clinical evidence

Returning patients to normal daily tasks, workplace, and recreational activities pain-free,
and with minimal down-time.



Orthocell has treated 700 patients during clinical development of Ortho-ATI[™]



Patients are aged 18 to 77 years of age, and average 53 years



Patients have experienced an average of two years chronic pain and three failed treatments. At this point, the only remaining treatment option is generally elective surgery.



Living with a chronic pain has a significant impact on quality of life and their capacity to participate in the workforce.

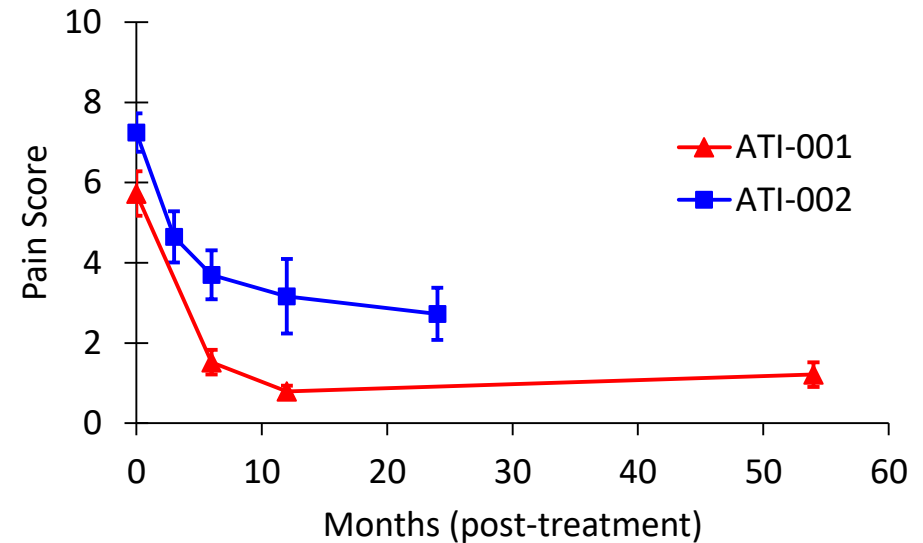
Ortho-ATI[®] : reducing pain

Ortho-ATI[™] treatment provides a meaningful and lasting reduction in pain

Clinical studies of Ortho-ATI[®]

Clinical Study Results

- **Reduction in pain** - Patients in clinical studies of Ortho-ATI[®] for lateral epicondylitis (ATI-001) and gluteal tendinopathy (ATI-002) experienced a significant reduction in pain within 6 months of Ortho-ATI[™] treatment
- **Sustainable outcome** - The improvements in pain were maintained in all studies, for up to 4.5 years post-treatment in the case of ATI-001 and two years post-treatment in ATI-002.



Pre-and post-treatment VAS pain score in clinical studies of Ortho-ATI for lateral epicondylitis [ATI-001], gluteal tendinopathy [ATI-002].

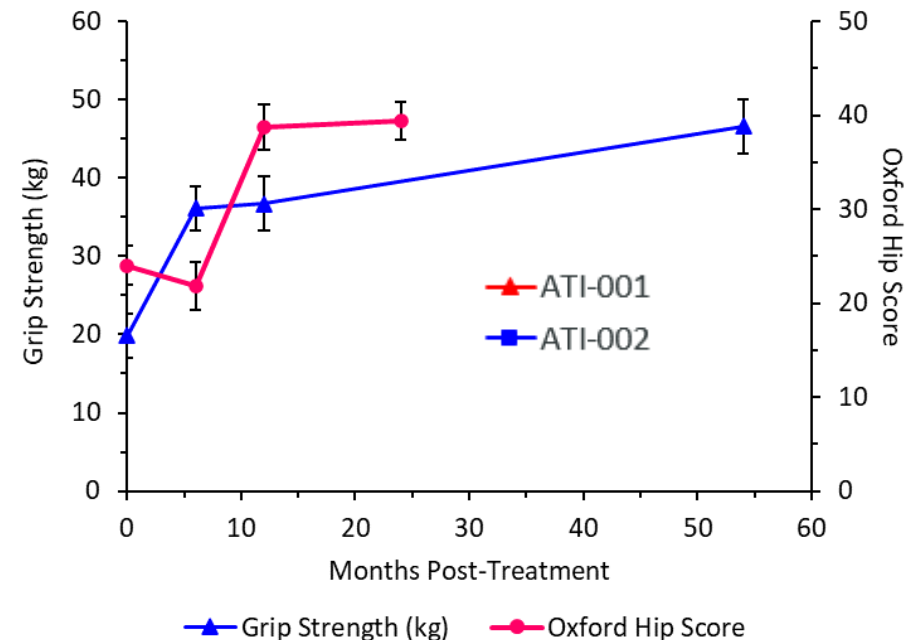
Returning to function

Ortho-ATI[®] treatment improves strength and function

Clinical studies of Ortho-ATI[®]

Clinical study results

- **Long term increases in strength** - Patients in clinical study of Ortho-ATI[®] for lateral epicondylitis (ATI-001) mean grip strength at baseline was 19.85kg, improving to 37.38kg at one year and 46.60kg at final follow-up.
- **Sustainable increases in function** – Patients in clinical study of Ortho-ATI[®] for gluteal tendinopathy (ATI-002) mean OHS improved from 24.0 at baseline to 38.8 points at 12 months, and 39.4 at 24 months post-treatment.



Pre-and post-treatment disability and function scores in clinical studies of Ortho-ATI for lateral epicondylitis (ATI-001), gluteal tendinopathy (ATI-002).

Ortho-ATI[®] : Upcoming US milestones

Orthocell is focused on completing current clinical studies¹ and preparing for US market entry

Randomised shoulder tendon clinical study results

- First high-quality RCT completed in the Rotator Cuff indication
- Results expected in Q4 2021
- US\$2.8b market opportunity, approx. 470,000 rotator cuff patients per year in the US alone

US Next Steps

- Well positioned to become the first FDA approved injectable cell therapy in orthopaedics for the treatment of chronic tendon injuries
- US regulatory strategy to be pursued to enable rapid approval by FDA

Results
expected in
Q4 2021

1. Orthocell is undertaking two RCT's. The first is targeting the rotator cuff indication comparing Ortho-ATI to corticosteroids (30 patients) – results are due in Q4, 2021. The second is targeting the elbow (LE) comparing Ortho-ATI to surgery (50 patients) with recruitment 92% complete.

Mark LeCras, Ortho-ATI
patient



Striate ™

More than a barrier
membrane



Striate+™ premium dental membrane

- Striate+ is a sterile, resorbable collagen membrane for use in dental bone and tissue regeneration procedures.
- Striate+ is designed to protect the bone defect space from ingrowth of gingival tissue, to provide a favourable environment for osteogenesis and to assure reliable formation of high-quality bone.
- Approved in the US, EU and AUS



1. Preparation of repair site. Defect site is filled with bone graft



2. Striate+ placed over defect and implant abutment installed



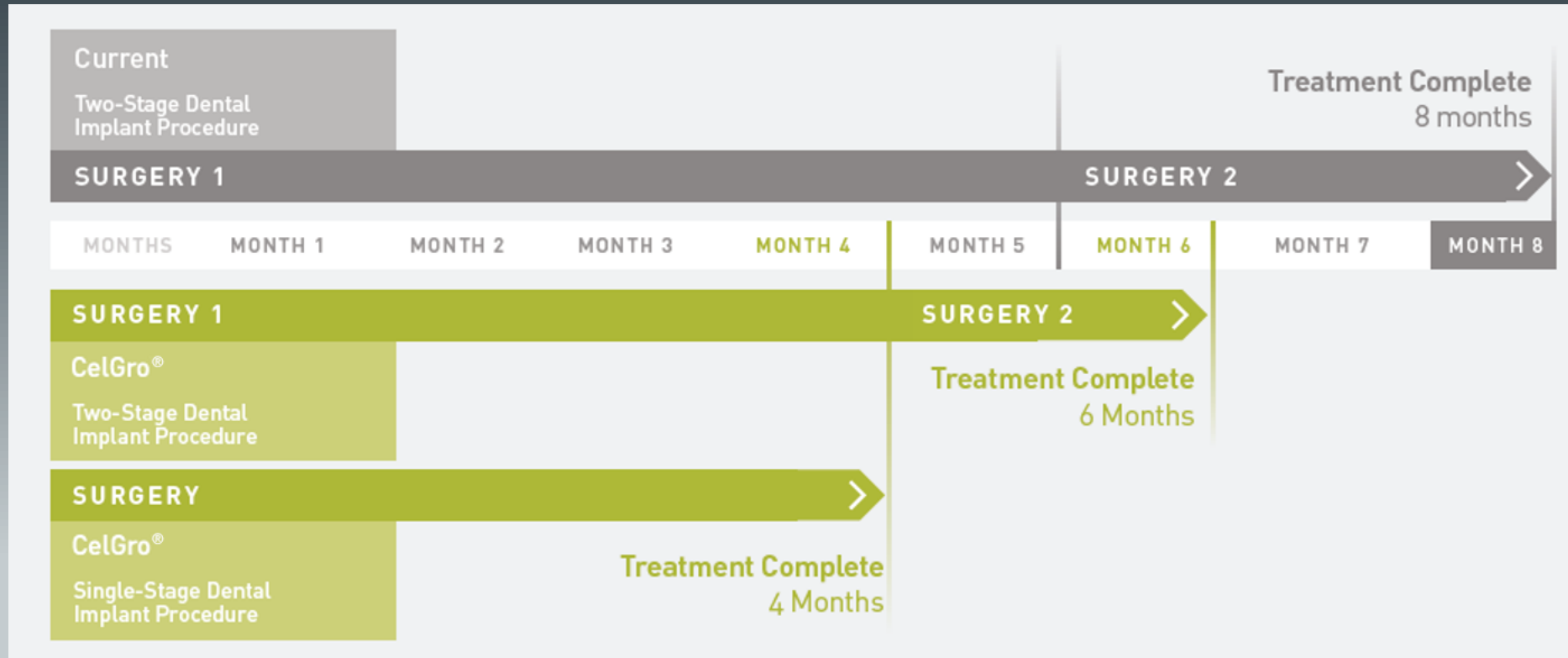
3. Wound closure



4. Crown placement 3-6 months later

Striate+™: better results sooner

Patients treated using Striate+™ successfully generated enough new bone to stabilise their implants and complete their treatment in approximately 4 months, compared to the 8 months required for standard dental implant treatment¹.



1. 1. CG-002 Study of CelGro membrane in guided bone regeneration around exposed dental implants. ACTRN12615000027516. TGA trial number 2015/0171

Striate+™: world class KOL group

USA / AUS



Justin Bonaventure
Louisiana



Anthony Feck
Kentucky



Kathy Frazar
Texas



Maria Lopez Howell
Texas



David Little
Texas



Marc Nevins
Massachusetts



Sammy Noubissi
Maryland



John Phillips
Oklahoma



Pamela Ray
Texas



Amanda Seay
South Carolina



Lou Shuman
Washington DC



Brent Allan
Australia

UK / EU



Nick Fahey
Reading



Elaine Halley
Scotland



Céline Higton
London



Giuseppe Luongo
Rome



Sinead McEnhill
Northern Ireland



Massimo Simion
Milan

Striate+™: dental path to partnering

Executing a strategy to engage high quality partners to manage the distribution and marketing of Striate+™ - *10% market share equates to AU\$35M revenue per annum¹*

Path to partnering

Market development activities

 <p>Clinician advocacy program</p>	<ul style="list-style-type: none"> • Product advocacy and education led by Orthocell's KOL's with significant digital following (e.g. interactive webinars and podcasts) • Increase key dental editorial coverage • Support key dental associations (UK – association of dental implantology, ADI) and education academies (UK – Fitz Fahey Academy) • Inclusion in dental education books written by Orthocell's KOL's • Seattle study club program – 270 affiliates globally, 5,700 dental surgeons, specialist GP's and periodontists, 8,000+ EDM database
 <p>Build awareness amongst leading clinicians and potential partners</p>	<ul style="list-style-type: none"> • Digital marketing engagement with clinicians • Increase key dental editorial coverage • Clinical conference participation • Targeted clinician workshops • Direct product representation
 <p>Grow body of clinical evidence and product adoption</p>	<ul style="list-style-type: none"> • Gain reimbursement from private insurers • Data generation e.g. post-market clinical follow ups • Publication in high impact journals

1. Orthocell's estimate based on 350,000 units sold @ competitive transfer prices per product size in target jurisdictions (US, EU and AU).



Remplir™

Revolutionising nerve repair

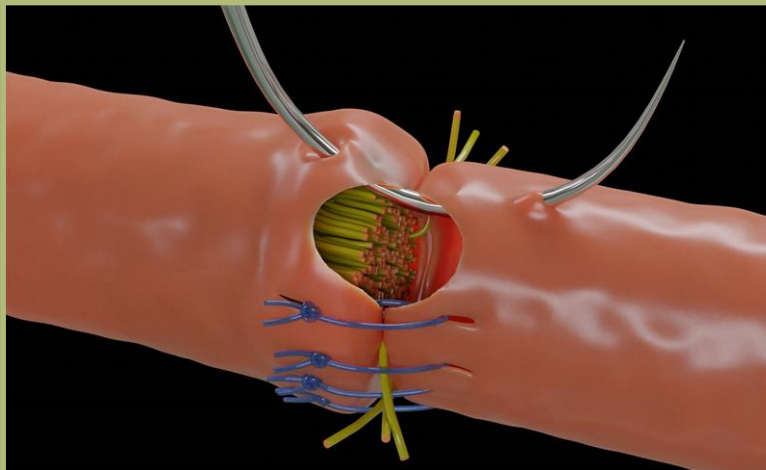


Traditional repair outcomes are suboptimal

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

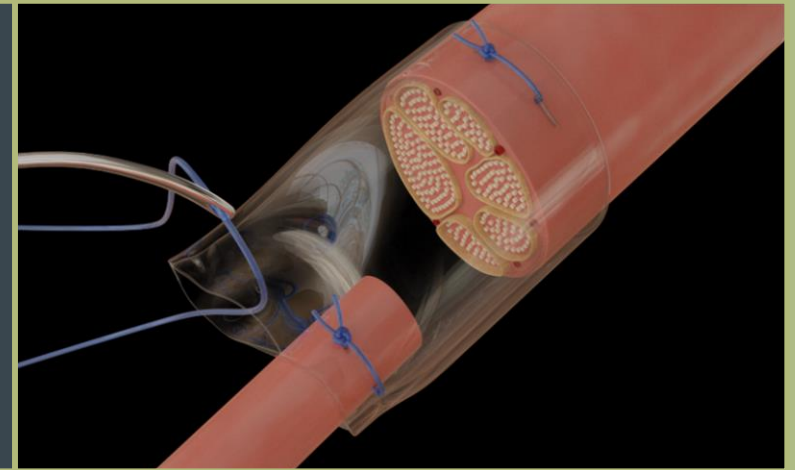
Direct suture

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 rate¹



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

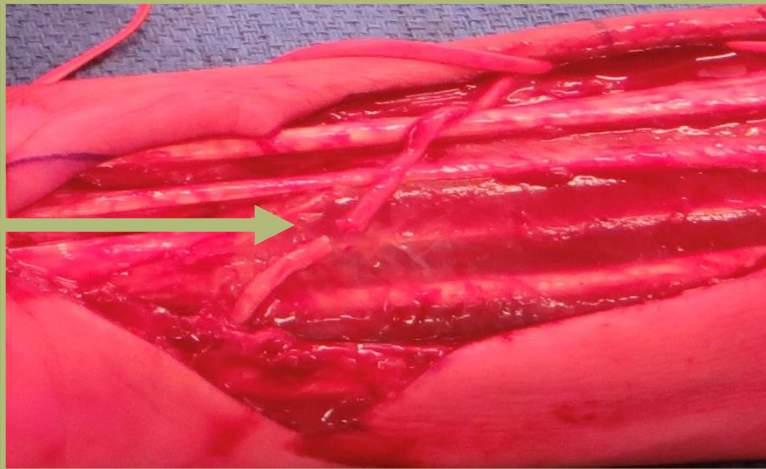
1. Weber, et al. A randomized prospective study of polyglycolic acid conduits for digital nerve reconstruction in humans. *PlastReconstrSurg.* 2000; 106(5): 1036-1045.

Remplir™: nerve transfer surgery

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

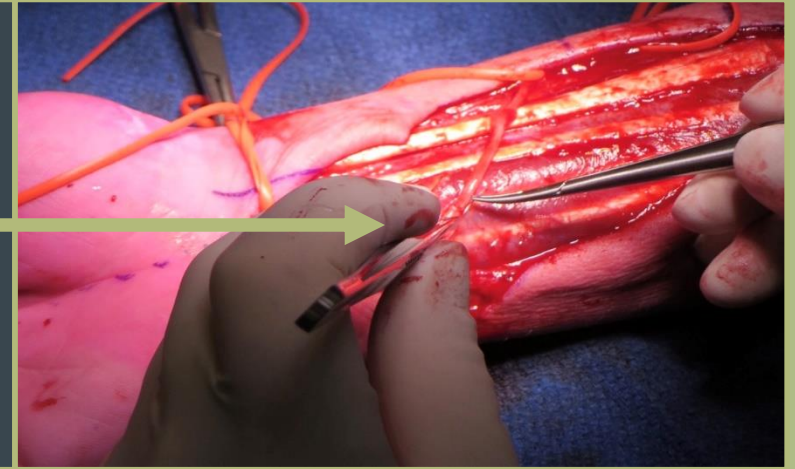
1

Transferring superficial radial to ulnar nerve



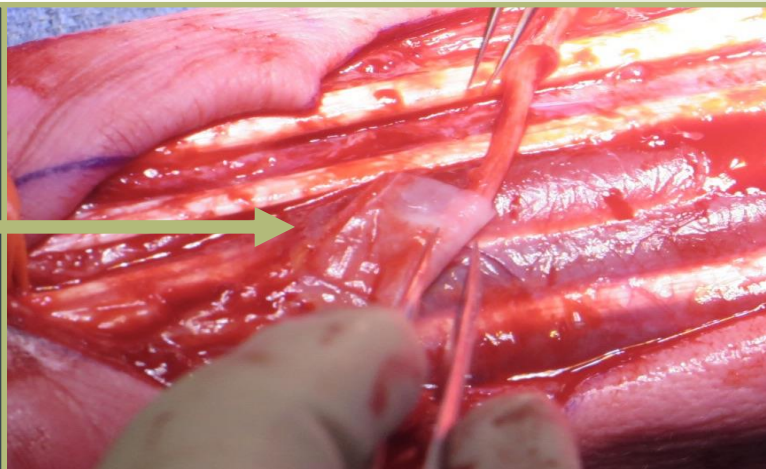
2

Placing a stay suture to oppose nerve ends



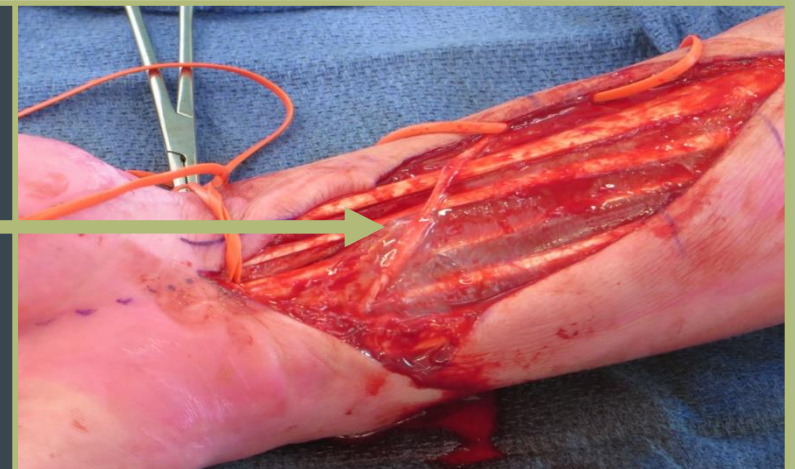
3

Wrapping Remplir around nerve ends to create a customised conduit



4

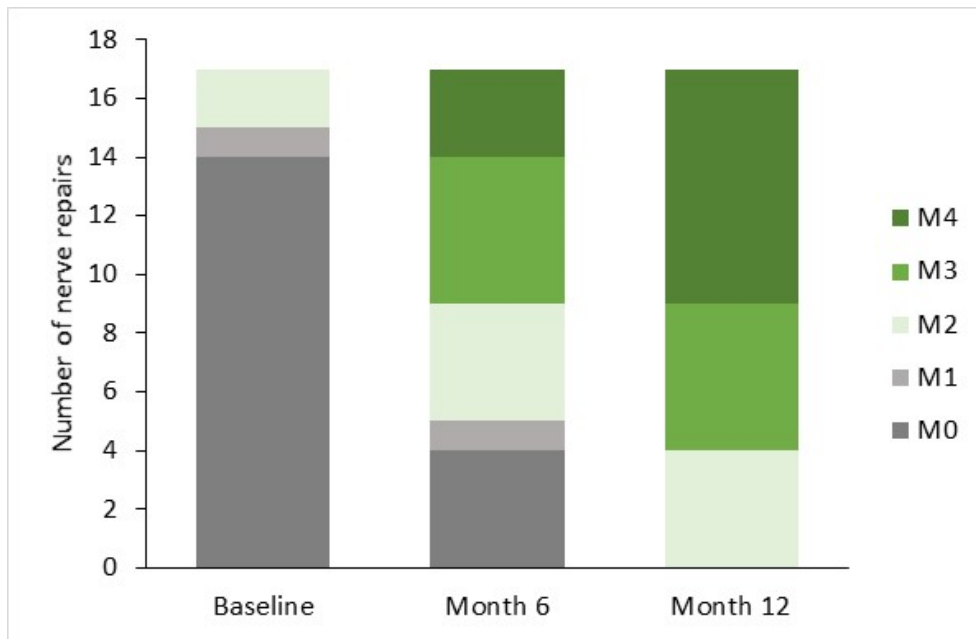
Remplir guides and supports nerve repair



Remplir™: 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.

- 75.8% of all nerve repairs (25 of 33) in the clinical study resulted in functional recovery (MRC grade 3 or 4¹)
- Quadriplegic patients regain independence - brushing teeth, drinking from a cup, and transferring into and out of a wheelchair without assistance

Leading Australian orthopaedic nerve specialist and clinical trial lead, Dr Alex O’Beirne, said “We are now seeing a consistent return of arm and hand function following nerve transfer surgery with Remplir. The quadriplegic patient results are particularly promising, with improved results at 12 months post treatment compared to the literature. **Remplir is increasing the success rate and efficiency of nerve transfer surgery.**”

**Meet Adrian Walsh, a 43-year-old father
of three who was diagnosed with
quadriplegia after he broke his neck
in a mountain bike accident
in June 2017.**

Remplir™: nerve repair market opportunity

Remplir's addressable market in peripheral nerve repair is estimated to be worth more than **>US\$7.5 billion per year.**

Orthocell is focused on executing its regulatory program to gain approval in AUS and the US.



Clinical trial patient Adrian Walsh (far left) wheelchair rugby national champion – following treatment with Remplir

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.

Upcoming catalysts¹

Ortho-ATI

Ortho-ATI v Corticosteroid (RCT) study results	4Q CY2021
Ortho-ATI v Surgery (RCT) rec't complete (estimate)	1Q CY2022

Striate+ premium periodontal membrane

Expand manufacturing capacity	4Q CY2021
First US KOL order	4Q CY2021
Engage US marketing and distribution partner/s	CY2022

Remplir premium nerve wrap

Australian market authorisation estimate	CY2022
Final 24-month results of all patients in the nerve regeneration study	2Q CY2022

Pipeline

Collagen rope pre-clinical study	CY2022
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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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