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Company Presentation

30 August 2024

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Orthocell at a glance

Well-funded Australian medical device company with growing international revenue and US approval of breakthrough nerve repair device pending

BEST IN CLASS PRODUCTS APPROVED IN EIGHT JURISDICTIONS

Bone / Striate+: US, EU/UK, AUS and CAN
Nerve / Remplir: AUS and NZ

MANUFACTURED IN AUSTRALIA

Scaled facility certified to manufacture in major jurisdictions under strict quality standards (i.e. MDSAP and MDR)

GROWING REVENUE

FY24 revenue of $6.76 million, up 30.76% from the previous year (FY23) of $5.17 million. 1Q FY25 displaying strong growth and ahead of expectations

REMPLIR PATH TO PARTNERING

US advisers appointed to secure large global distribution partner

NO DEBT, NO ROYALTIES

AU$20.60m cash at bank and the Company retains all revenue benefits maximising cashflow to the Company

REMPLIR USA APPROVAL 1Q CY25

Remplir breakthrough nerve repair product is funded to US approval and FY25 market launch

Corporate snapshot

Current analyst risk-adjusted valuations per share of $1.00 and $1.28/sh

ASX: OCC TRADING INFORMATION

Share Price (30 day VWAP)	**$0.38**
12 month low/high	$0.33/$0.43
Shares outstanding	209M
Market Capitalisation	**~$80M**
Cash (30 Jun)	$20.60M
Debt (30 Jun)	Nil

SUBSTANTIAL SHAREHOLDERS

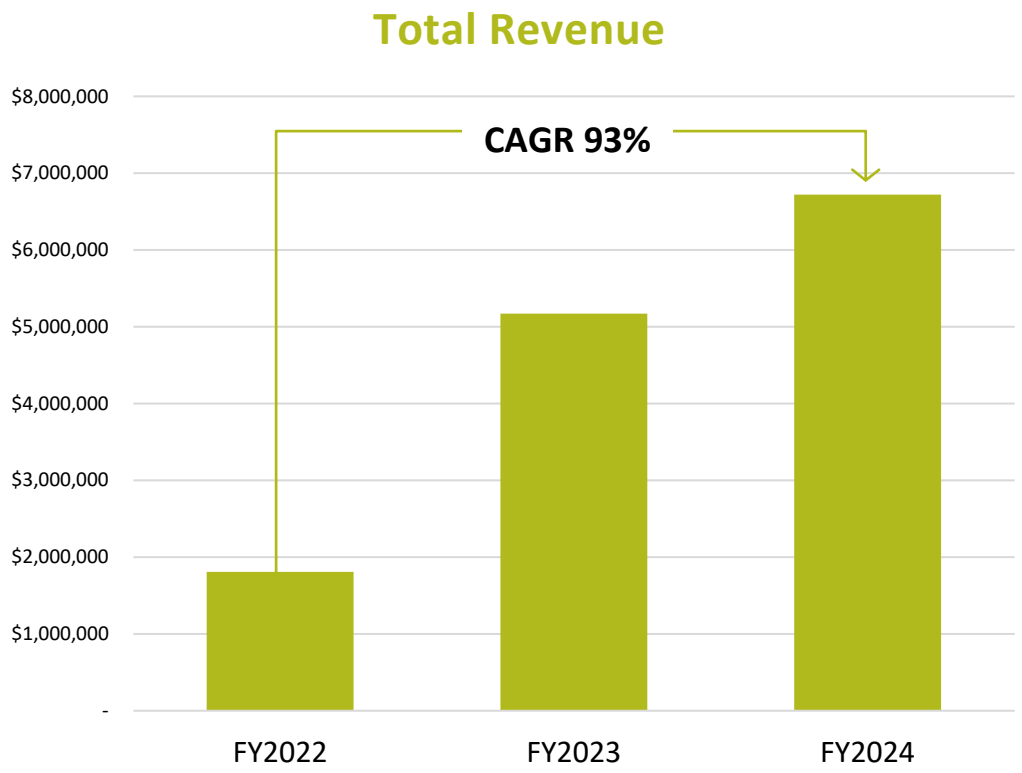
Shareholder	%
Founders & Management	~13%
Institutions & HNW's (Mr Chris Ellison, Mr Rod Jones, Mr Michael Malone, the McCusker Family & Merchant Biotech)	~8%

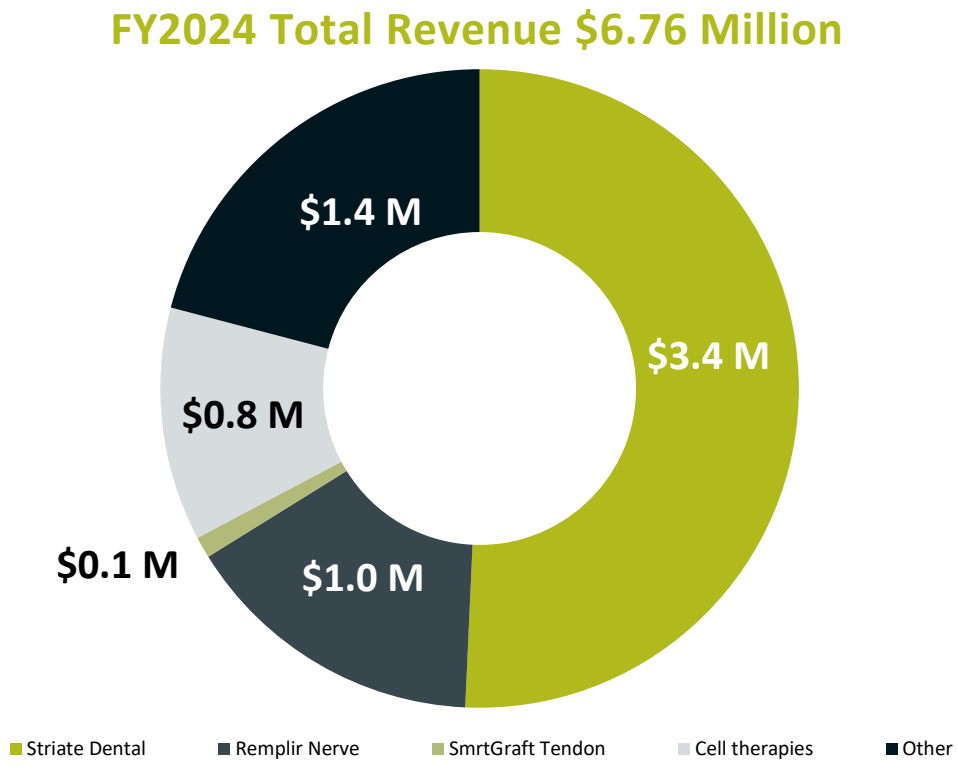
AU$20.60m

Cash at bank and funded beyond US approval of Remplir™

Growing Revenue

FY24 revenue of $6.76 million, up 30.76% from the previous year (FY23) of $5.17 million.
Striate+™ and Remplir™ ahead of expectations





High-profile Board

Recent appointments of John Van Der Wielen and Professor Fiona Wood AM places Orthocell in a strong position to drive its products into global markets and accelerate revenue growth

Mr John Van Der Wielen
Independent Non-Executive Chairman

- 35+ years experience in international financial services including large funds management, insurance and private banking
- Former CEO of HBF with annual revenues over $2B
- Extensive corporate strategy, institutional and strategic investor engagement and M&A transaction experience

Mr Paul Anderson
Founder and Managing Director

- 25+ years in regenerative medicine industry
- Former MD at Verigen, successfully commercialised cartilage repair cell therapy (MACI)
- Extensive experience in product development, navigating regulatory pathways, international market launches, medical education and sales force leadership

Dr Rravi I. Thadhani
Independent Non-Executive Director

- 30 years of specialist experience working in US healthcare sector - highly regarded executive, medical administrator and researcher
- Former professor of medicine at Harvard Medical School and chief academic officer at Mass General Brigham hospital, where he oversaw a $2.3 billion research enterprise
- Extensive US regulatory experience and commercialisation of devices and therapeutics

Professor Fiona Wood AM
Independent Non-Executive Director

- 30+ years experience as a plastic and reconstructive surgeon
- Inventor of RECELL "spray on skin" treatment, now supplied by Avita Medical Inc, a AU$450M dual-listed company with operations in 30+ countries including the US
- Unrivalled track record in development and commercialisation of innovative regenerative medicine products

Hon Kim Beazley AC
Independent Non-Executive Director

- Unrivalled experience engaging strategic partners in the US – highly regarded politician, executive and strategic adviser
- Former Australian US Ambassador and Governor of Western Australia, Deputy Prime Minister, and Minister for both Defence and Finance
- Extensive experience representing both public and private interests for Australia

SMRT™ Manufacturing

DEVELOPING AND MANUFACTURING BIOLOGICAL MEDICAL DEVICES

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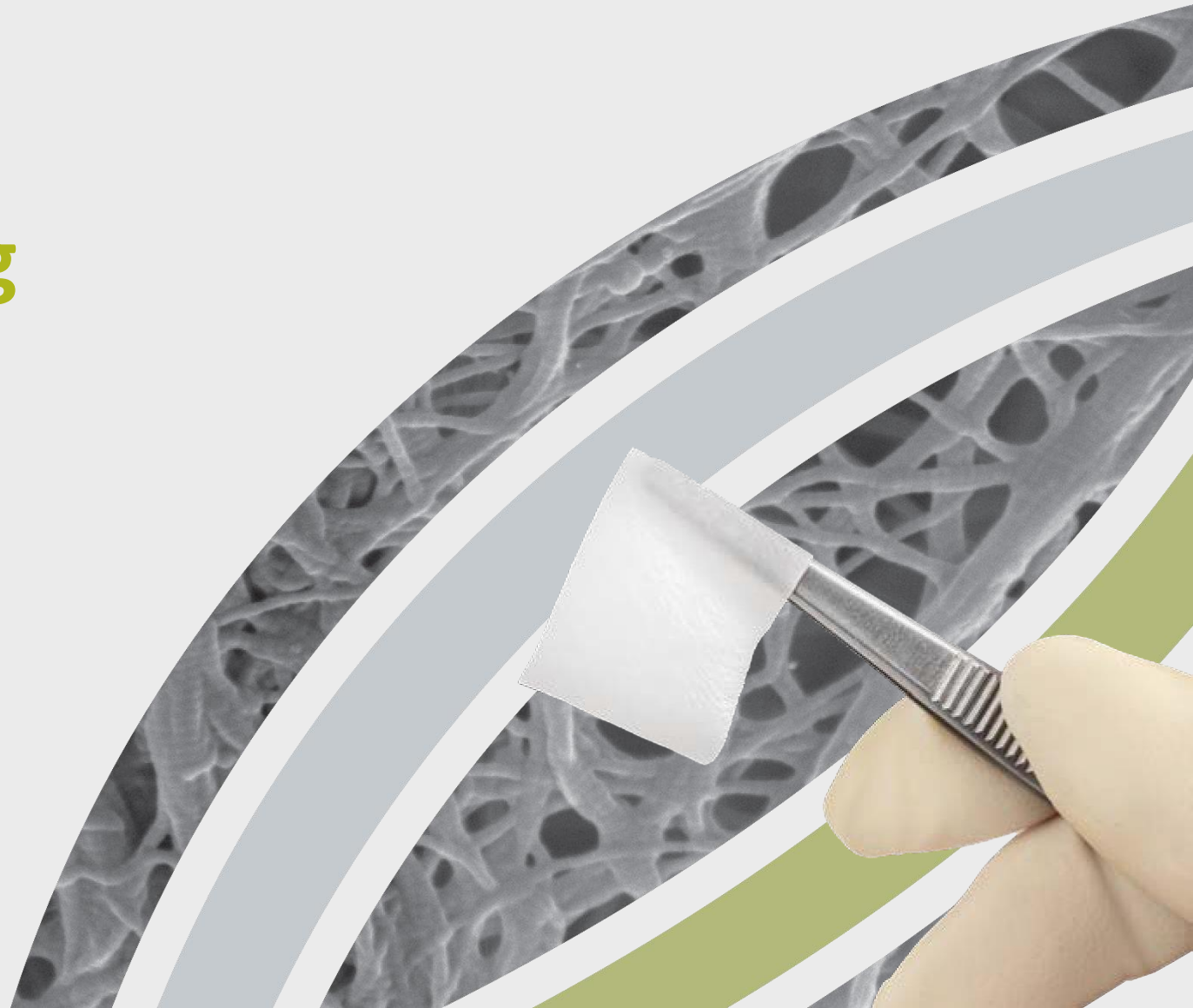


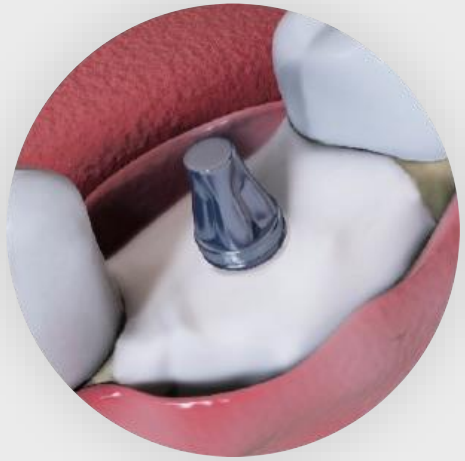
Collagen medical device platform

Our collagen medical device platform is comprised of a range of acellular, type 1 collagen devices for the surgical repair of bone, nerve, tendon and cartilage

BONE

Striate+™ membrane

Dental bone and tissue repair

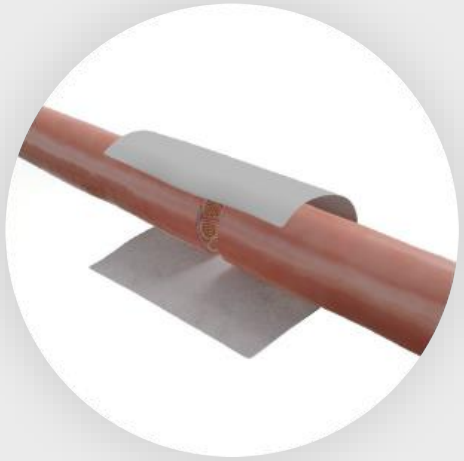


Revenue generating in
US, EU/UK and AU

NERVE

Remplir™ nerve wrap

Peripheral nerve repair



Revenue generating in
AUS & NZ

TENDON

SmrtGraft™ scaffold

Tendon repair

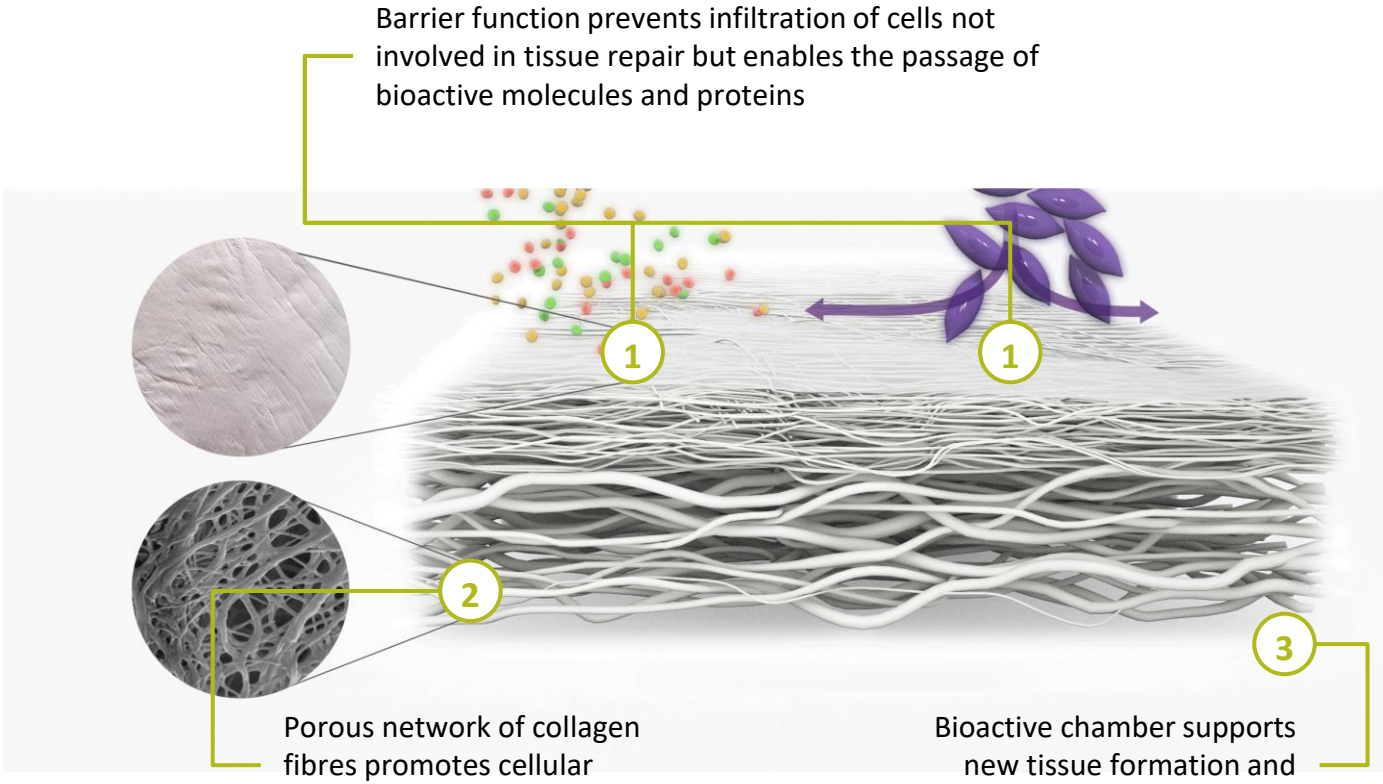
AUS launch
CY 2025

SMRT™ manufacturing

Orthocell develops and manufactures innovative collagen medical devices that deliver the highest quality surgical repair of bone, nerve, tendon and cartilage

SMRT™ manufacturing process

- **Pure collagen**
  Decellularization process removes all cellular and genetic material
- **Mimic human collagen**
  Natural collagen structure is preserved creating the ideal environment for cellular attachment and proliferation
- **No immunogenic reaction**
  Devices integrate and degrade commensurate with the tissue healing process



Australian manufacturer

Scaled facility certified to manufacture medical devices to major jurisdictions under strict international quality standards (i.e. MDSAP and MDR)

Remplir™

REDEFINING NERVE REPAIR

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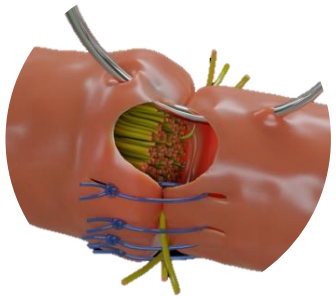
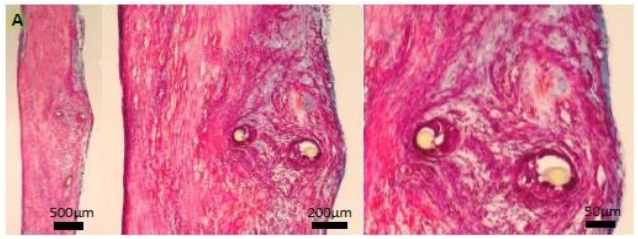
Remplir™: Nerve repair breakthrough

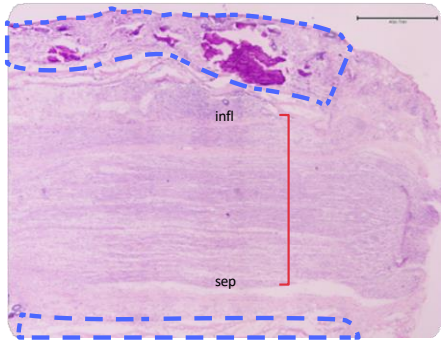
Current repair methods can place delicate nerve tissue under tension, causing scarring, fibrosis and neuroma formation

1860s
Suturing

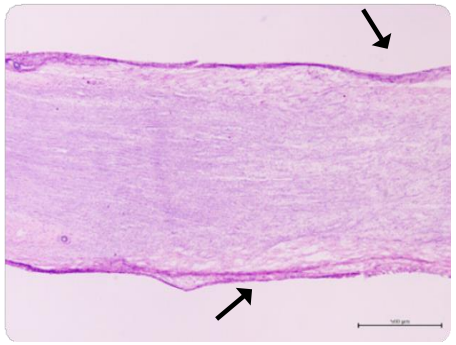




2000s
Conduits



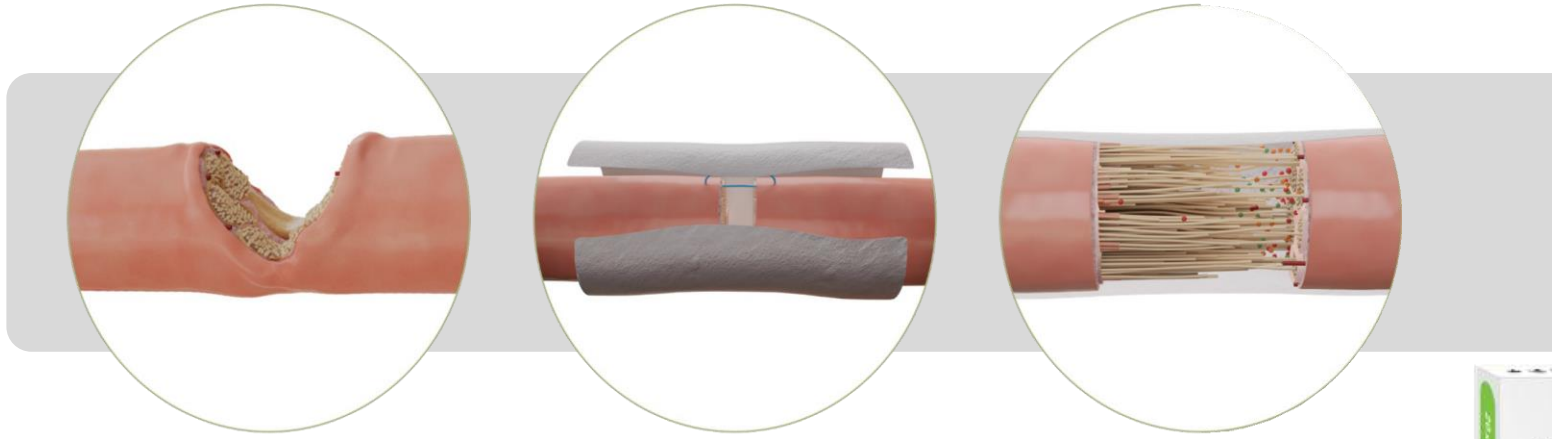
2020s
Next generation



Success Rates	**50-70%**	**55%**	**85%**

Remplir™: Redefining nerve repair

Collagen nerve wrap approved and reimbursed in Australia.
Intended for use in peripheral nerve repair



- ✓ Exceptional handling characteristics
- ✓ Reducing sutures
- ✓ Mimics epineurium (nerve outer layer)
- ✓ Returns nerve to pre-injured state

GUIDING PREDICTABLE OUTCOMES IN PERIPHERAL NERVE REPAIR

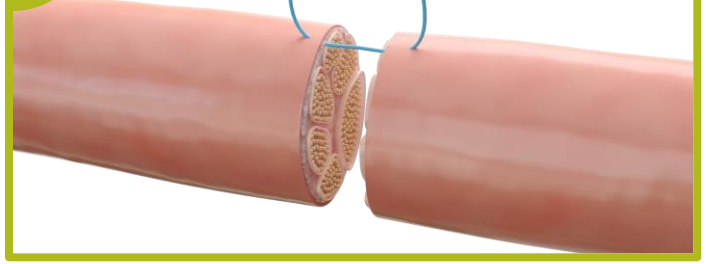
Remplir™: surgical technique

A breakthrough product guiding predictable outcomes in peripheral nerve repair and return of muscle function

1

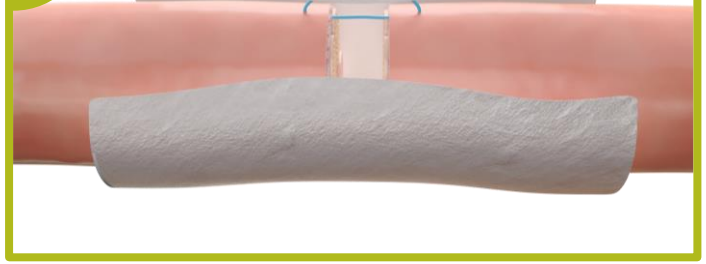
Damaged peripheral nerve after traumatic injury to limb

2



Damaged section of nerve is removed, and ends bought together without tension

3

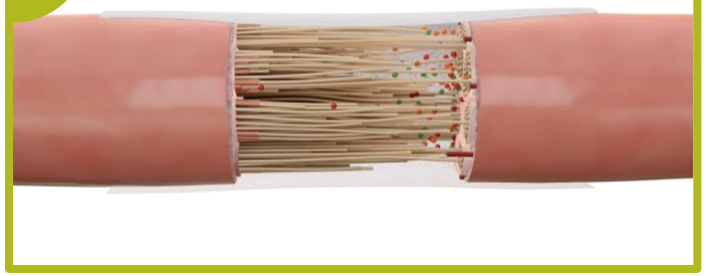


Remplir is wrapped around nerve, reducing suture requirements and facilitating optimal coaptation

4

Remplir easily confirms to the repair site while mimicking the nerve's natural epineurium

5



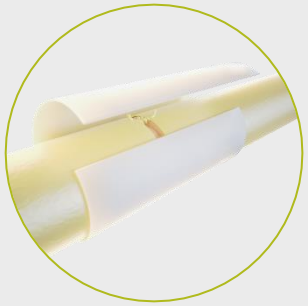
Remplir creates a protected healing environment allowing new axons to reconnect

6

Healed nerve restores function to affected limb

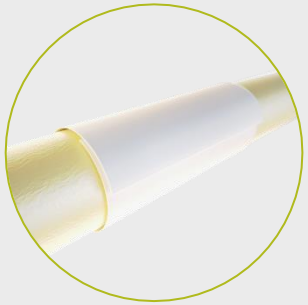
Remplir™: indications

Remplir™ is the only device that can be used for either connecting severed nerves, protecting damaged nerves or capping amputated nerves



CONNECT

Trauma: motor vehicle, power tool, surgical injuries, sports and military related accidents



PROTECT

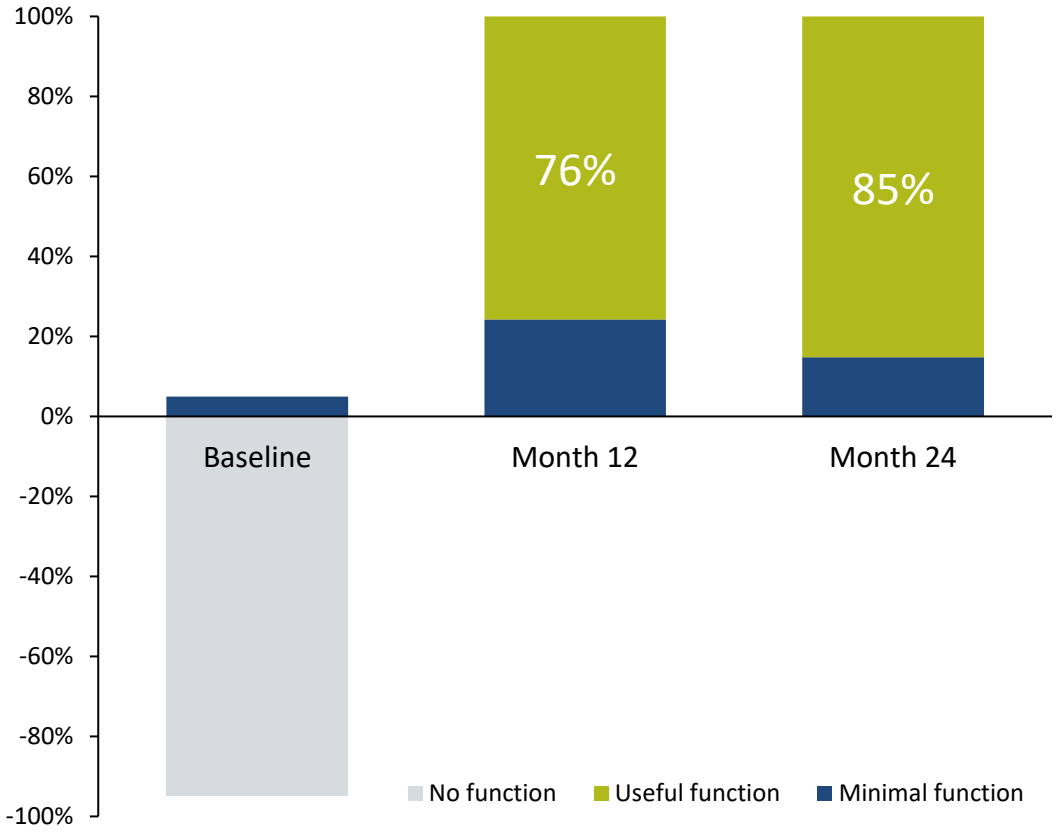
Compression: blunt trauma, revisions surgeries (e.g. carpal/cubital tunnel)

CAP

Amputation: amputations, stump neuroma, mastectomies, schwannoma

Remplir™: compelling clinical results

Patients regained voluntary muscle movement within 12 months, increasing strength and range of motion at 24 months



We are now seeing a consistent return of arm and hand function following nerve transfer surgery with Remplir™. Remplir™ is increasing the success rate and efficiency of nerve transfer surgery.

- Leading Australian orthopaedic nerve specialist and clinical trial lead, Dr Alex O'Beirne

Useful Function
Voluntary movement with improved strength and range of motion

Minimal Function
Voluntary movement restored, limited strength and range of movement

No Function
No voluntary movement

FINAL RESULTS

85% (23 of 27) of nerve repairs resulted in functional recovery of muscles controlled by the repaired nerve

Click to play video

Australian Remplir™ case study opens up global nerve repair opportunity

Injury

- Mountain bike accident
- C5 quadriplegia

Impact

- No arm strength and no movement in fingers and thumbs
- Life in a wheelchair was difficult

Surgery

- Nerve transfer using Remplir™

Outcome

- Better fine motor control and can do things with two hands
- Playing wheelchair rugby and driving his car

Remplir™ patient:
Adrian Walsh

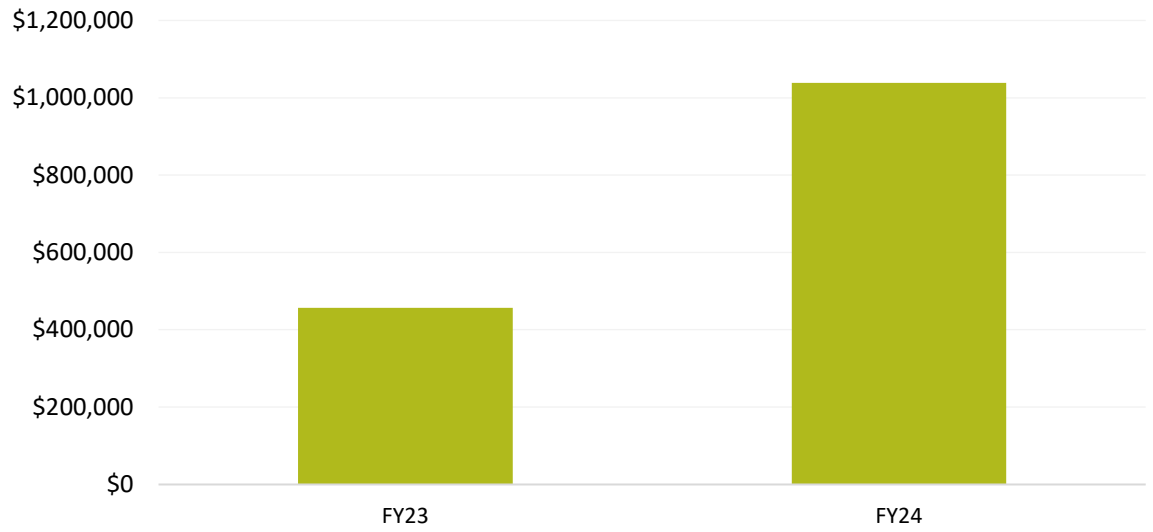
This treatment has made a world of difference to me. The increased strength and mobility in my arm and hand has really boosted my independence. I am contributing more around the home and can help my wife and kids – it feels good.

- Adrian Walsh, Remplir™ patient

Successful launch with growing revenue

AUS commercial launch[1] of Remplir™ with Device Technologies, reimbursed in the private healthcare system in November 2022, with sales unit volumes exceeding expectations

Remplir product revenue since AUS market launch



- **127% growth in Remplir™ revenue from $457K in FY23 to $1.04M in FY24**
- **Product sales to Device Technology significantly exceeded guidance –** over 130 orthopaedic and plastic reconstructive surgeons
- **Adoption drivers -** enables less suturing, creation of the optimal healing microenvironment and facilitation of free gliding within the repair site during the critical healing period

1. Orthocell supplies Device Technologies (DVT) with Remplir™ products, and DVT exclusively market and distribute Remplir™ in Australia.

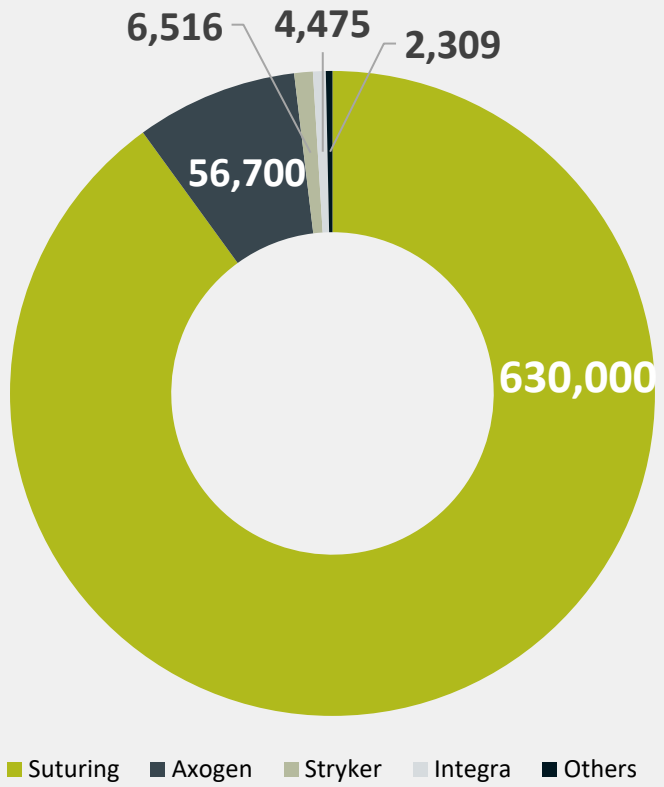
The US is the largest market

Approval anticipated 1Q CY25

Over 700,000[1] peripheral nerve repair procedures in the US per year, 90% undertaken using suture only method.

- Current devices are not widely adopted due to suboptimal outcomes – Axogen, Integra and Stryker collectively sell ~70k units per year (10% of procedures)
- Remplir US (510K) regulatory study on track for completion in 4Q CY24. US approval anticipated 1Q CY25

Annual US nerve reconstructions



1. Referenced papers used to estimate peripheral nerve procedures in the US per annum. Papers used included both US and OUS databases and studies

Remplir™: Path to partnering

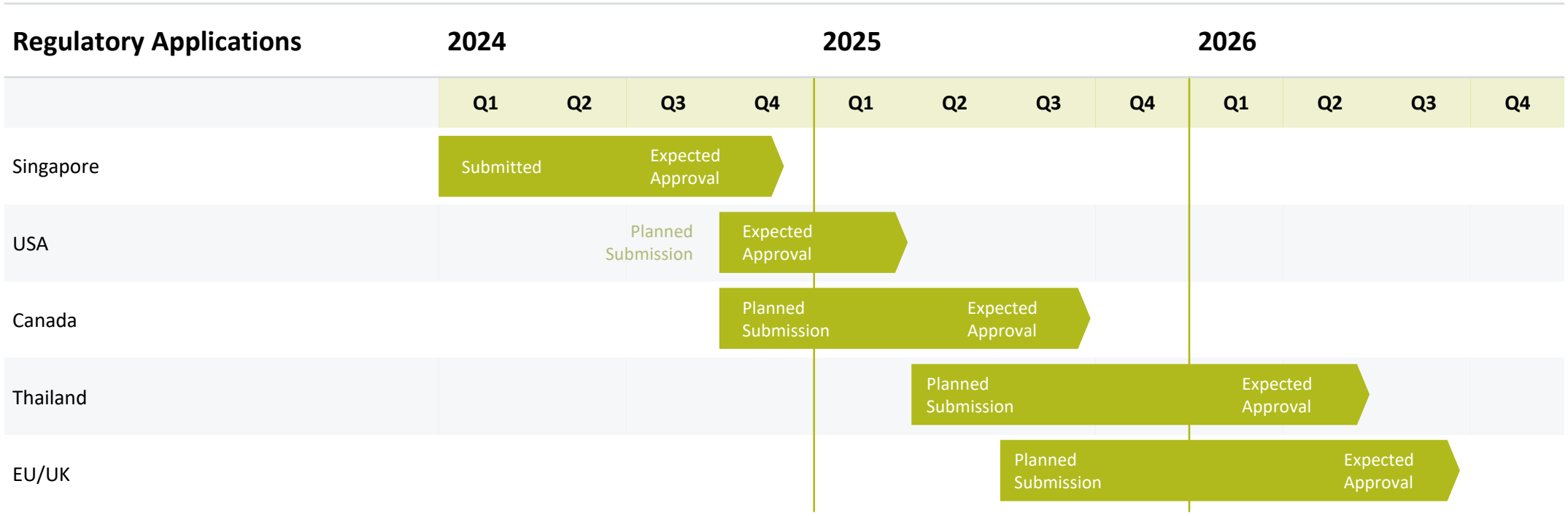
Orthocell is underpinned by a proven business model for innovating, developing, launching and successfully partnering medical device products

Scale Organisation	US Approval	Brand Ambassadors	Data Package	Sales and Marketing
Executive team	Pilot study	Scientific narrative	Published preclinical	Positioning strategy
Manufacturing facility	Pre-submission meeting	KOL panel design	Published clinical	Pricing strategy
Quality system	Animal surgeries	KOL engagement strategy	TGA approval	Customer segmentation
Third party logistics	In-life assessments	In-country collaboration	PMCF	Promotion plan
Organisational team	Data analysis	Centres of excellence	In country study	Launch collateral
ERP implementation	510k submission	Clinician advocacy program		Medical education program
Hire in-country team				US team training material
				Engage distributors
				Establish key accounts

Remplir™: Market Expansion

Regulatory approval for Remplir in Singapore anticipated in 2H CY24 with a further four applications planned in Canada, Thailand, EU & UK in the next 6-12 months

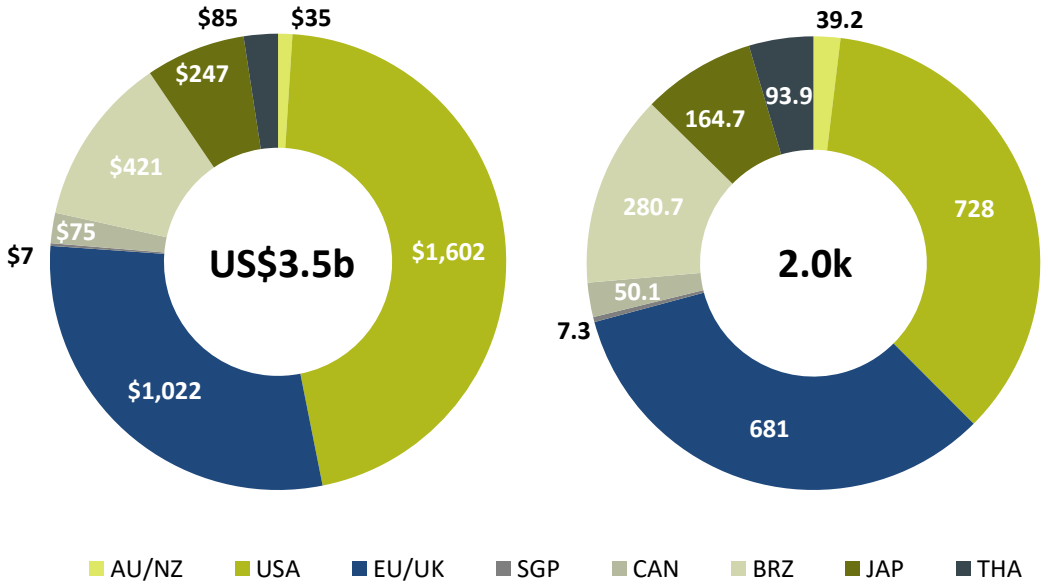
Approved in Australia and New Zealand



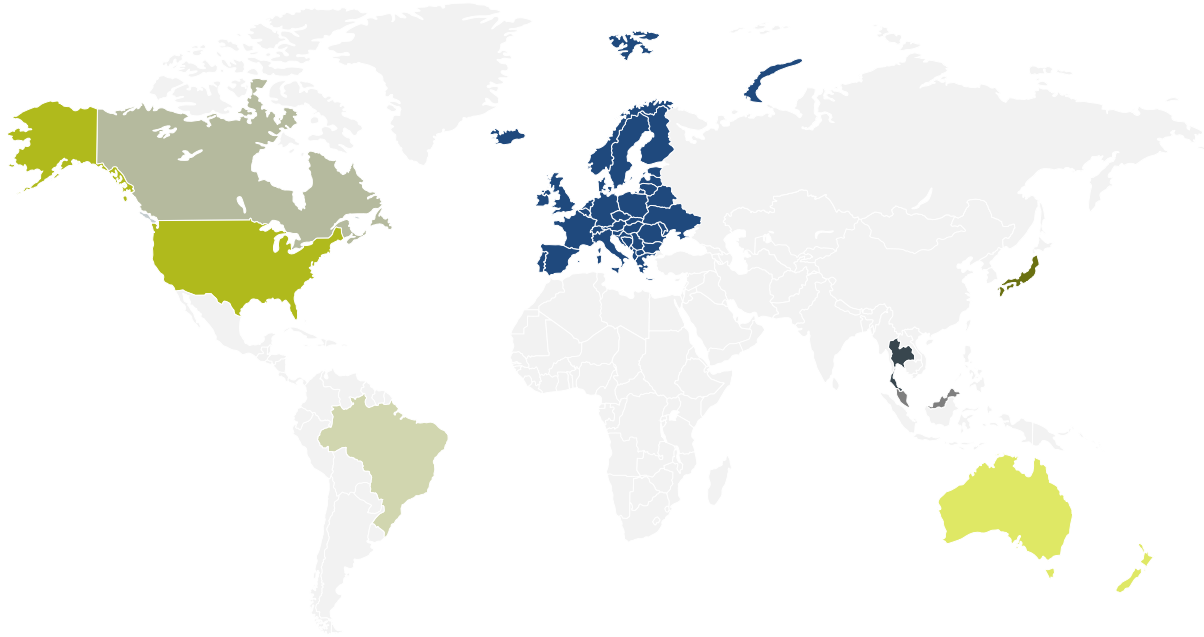
Remplir™: Large addressable market in nerve reconstruction

Remplir™ is a breakthrough product on track to be the global market leader in peripheral nerve repair – a retail market estimated to exceed US$3.5 billion[1] per annum

Total Addressable Retail Market (US$m)



Est. procedures p.a. at peak ('000)



20% Market Share would generate US $335 million in wholesale revenue to OCC

1. Addressable markets include AUS,USA, EU/UK, SGP, CAN, BRZ, JAP, THA. Referenced papers were used to estimate procedures per annum. Papers used included both US and OUS databases and studies

Striate+™

GROWING BETTER BONE IN DENTAL APPLICATIONS

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Striate+™ premium dental membrane

Next generation dental membrane for high quality bone repair

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

1

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

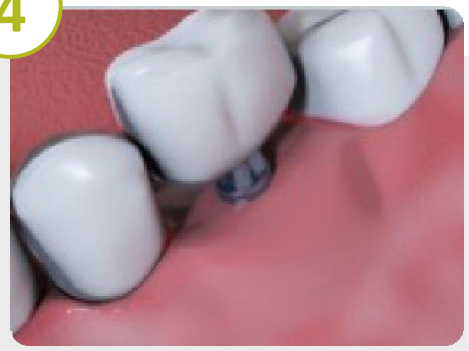
2

Striate+ placed over defect and implant abutment installed

3

Wound closure

4



Crown placement 3-6 months later

Striate+™ global license and manufacturing agreement

Innovation backed by world-class KOL's and an exclusive licensing deal with fifth largest global provider of dental products, BioHorizons

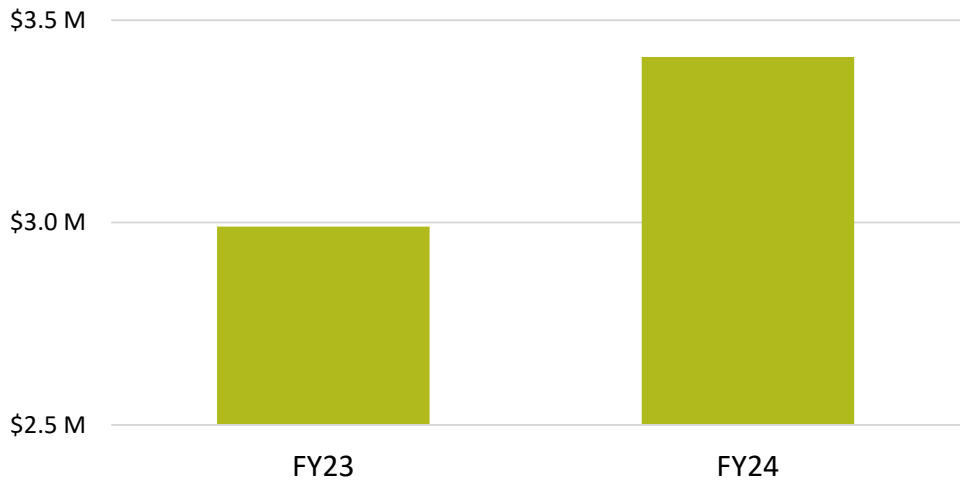
- **AU $21.5 million in upfront cash received net of fees** in consideration of the global license granted
- **Major validation of Striate+™ and the CelGro™ Platform** – opens the doors to the largest healthcare markets, reduces execution risk and provides a clear sight to revenue growth
- **Establishes the manufacturing business** - enables the scale up of manufacturing alongside the expected rapid growth in purchase orders from BioHorizons
- **Access to global distribution network – BioHorizons** is a global operator and a subsidiary of Henry Schein Inc. (NASDAQ: HSIC. US $11bn market capitalisation) enabling access to an international network of distribution partners. For e.g. First private label called perFORM™ launched by ACE Southern, September 18, 2023[1]

1. ACE Southern is a subsidiary of Henry Schein and will market and distribute perFORM™ on the same terms and conditions as BioHorizons is marketing and distributing Striate+™

Successful Striate+™ launch, revenue growing

US commercial launch[1] of Striate+™ dental barrier membrane in November 2022, sales unit volumes now exceeding expectations

Striate+ product sales + license revenue since US market launch



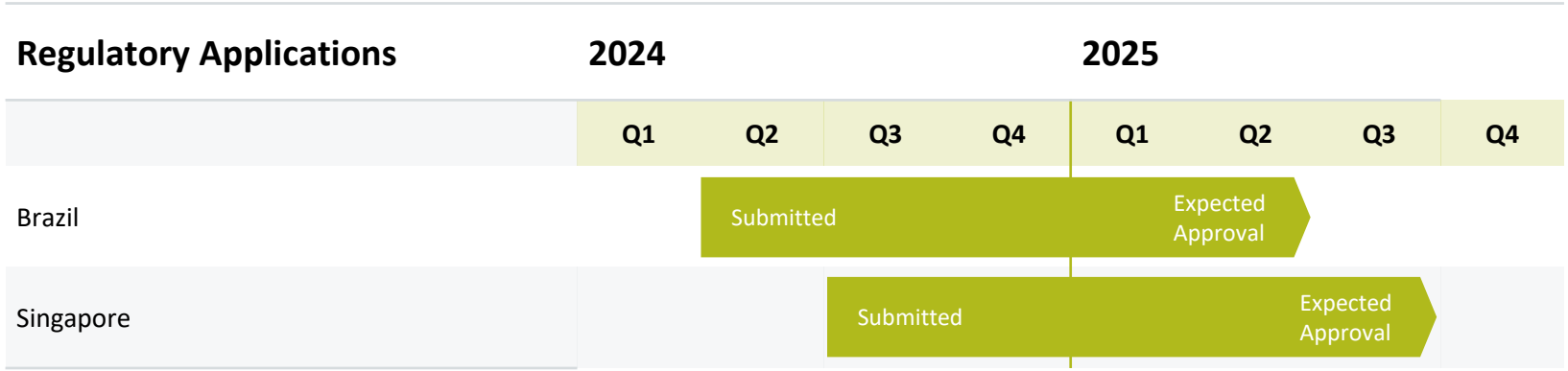
- **Gaining excellent traction and growing revenue in US, Europe, UK and Australia, supported by an outstanding 98.6% success rate from the Striate+ dental implant post-marketing clinical study**
- **14% growth in Striate+™ revenue from $2.99M in FY23 to $3.41M in FY24**
- **Forecast product sales to BioHorizons** now exceeded expectations, driven by a high performing distributor and the surgeons' preference for a high-quality dental membrane that is easier to use and facilitates better, more efficient bone growth

1. Orthocell supplies BioHorizons with Striate+™ products, and BioHorizons exclusively market and distribute Striate+™ globally.

Striate+™ Market Expansion

Orthocell is working with BioHorizons to accelerate access into the large markets of Brazil and Singapore and to achieve further regulatory approvals into multiple other markets where they have established accounts and/or distribution networks

Approved in Australia, USA, EU, UK and Canada



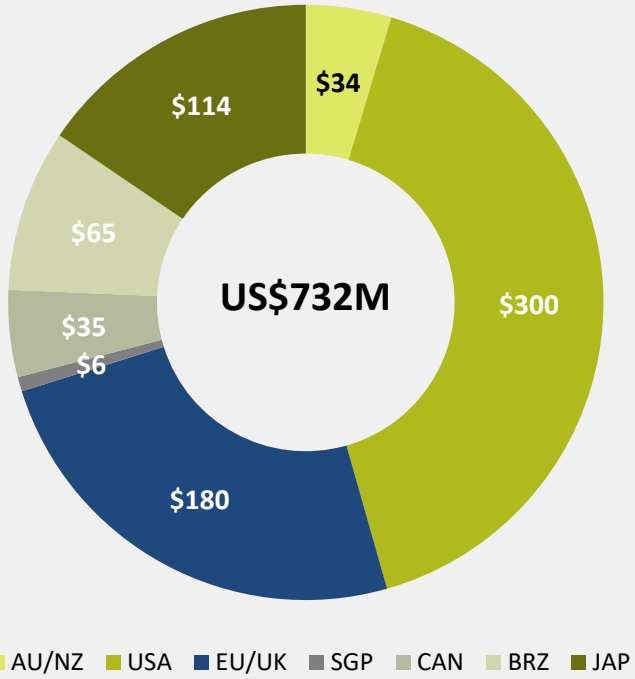
Striate+™ revenue growing in US, EU/UK & AUS – and beyond

Significant opportunity to secure 20% share of the US$732M[1] global dental barrier membrane market which would generate ~US $40 million in recurring wholesale revenue to Orthocell

Market Share Drivers

- Global distributor BioHorizons and ACE Southern[1] collectively control ~20% of the US market
- High quality product gaining excellent traction and growing revenue in US, Europe, UK and Australia
- Accelerating market access into the large markets of Canada, Brazil and Singapore.
- Achieving further Striate+ regulatory approvals into multiple other new large markets

Total Addressable Retail Market (US$m)



20% Market Share = US $40 million in wholesale revenue to OCC

1. ACE Southern is a subsidiary of Henry Schein and will market and distribute perFORM™ on the same terms and conditions as BioHorizons is marketing and distributing Striate+™

Upcoming catalysts[1]

Remplir international regulatory approval program

US registration study results	4Q CY24
US market authorisation	1Q CY25
Singapore product registration	4Q CY24
Canada product registration	3Q CY25

Striate international regulatory approval program

Brazil product registration	2Q CY25
Singapore product registration	3Q CY25

1. Timelines may be subject to change due to circumstances not under the Company's control

Pipeline

Advanced product portfolio with near term milestones and emerging pipeline. Orthocell is working with a US adviser to secure a partner to accelerate the commercialisation of the tendon cell therapy.

Product	Status	Next Steps	Multi-Billion US Markets
Medical Devices			
Ligament replacement	Successful pilot study completed	Pre-clinical and clinical study in development	**>200,000** procedures per year
Tendon Cell Therapy			
Rotator cuff	RCT shows significantly more effective than steroid injection	US partnering strategy in development	**>1,000,000** procedures per year
Lateral epicondye	RCT shows as effective, and potentially better than surgery		

Key Investment Highlights

Commercial-stage medical device company at revenue inflection point

Best in class products for Bone, Nerve and Tendon repair

Strengthened board with the appointments of highly experienced executives John Van Der Wielen, Professor Fiona Wood and Kim Beazley

$20.6M cash at bank, strengthened register, no royalty liabilities and funded to US approval of breakthrough nerve repair device

Near term value drivers including Remplir 510k study results Q4 CY24 and market clearance 1Q CY25

Authorised for release by:

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orthocell.com