

Annual General Meeting Addresses by Chair and Managing Director

Perth, Australia; 29 November 2024: Regenerative medicine company Orthocell Limited (ASX: OCC, "Orthocell" or the "Company") is pleased to attach copies of the addresses to be given by the Chair and Managing Director and Chief Executive Officer at Orthocell's Annual General Meeting (AGM) today.

Release authorised by:

Paul Anderson CEO and MD, Orthocell Ltd

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CHAIR'S ADDRESS

Fellow shareholders, thank you for joining me today, at the close of my first full financial year as the Chair of Orthocell. The 2024 financial year has been a very successful period of revenue growth and operational execution. Our revenue grew by 30.8% over the previous financial year, our first quarter in FY25 marked record growth, and the current quarterly trajectory bodes very well for a continued growth outlook. Our market capitalisation now exceeds ~\$194 million, which is over double what it was 12 months ago, and the Company's imminent entry into the USA market with Remplir™ will create a major scale opportunity.

There are not many opportunities to enter the Biotech sector in Australia with a company that has a strong balance sheet, no debt, growing revenues, unique patents, no ongoing cash diluting royalties and strong corporate governance. Strong corporate governance of companies is critical to sustainable success, and we are regularly reminded of this by both good and bad examples in corporate markets. I assure shareholders that strong governance is our highest priority, and I would like to take this opportunity, along with our CEO and MD Paul Anderson, to reinforce the governance and operational progress achieved in the last 12 months and to update investors on the next phases of our commercialisation strategy for Orthocell.

The board's approach is to govern Orthocell at the appropriate level for its size and to ensure our governance standards reflect our intention, which is to be a much larger and expansive company over the next few years. In the last 12 months we have completed a full board renewal and attracted world-class directors; implemented appropriate governance policies; and carried out a detailed independent remuneration review of the executive team and key management personnel. The current board of directors all have specific areas of expertise of direct benefit to the Company, and they have been actively assisting the management team to refine the strategy and achieve milestones. Our two founders, Paul Anderson (Chief Executive Officer and Managing Director) and Professor Ming Hao Zheng (Chief Scientific Officer), remain committed to being active participants in the next phases of the Company's growth.

This approach to governance was pivotal in the success of our recent \$17 million share placement at 60 cents, which I'm happy to report was significantly oversubscribed. The top 20 Orthocell shareholders are a robust register of long-term investors who have a genuine interest in a medical device company that has the potential to become an ASX 250 company. We now have ~\$32.8 million (as at 31st October) in cash reserves to sustain the business in its major expansion into the USA.

Our strategy to de-risk the Company by focusing on the most significant and immediate opportunities has borne fruit. The recent strengthening of the balance sheet, increased focus on regulatory applications for the global expansion of our core products Remplir™ and Striate™ has been rewarded with a growing share price and significantly more interest from institutional and sophisticated investors. We have also focused on delivering, alongside our distributors, quarter on quarter revenue growth. We expect this achievement to continue and accelerate with additional international market launches underway, and several regulatory submissions completed or pending approval.

Orthocell proudly manufactures its unique products in Western Australia which allows for the capture of the full profit margin. Australia is a globally trusted manufacturing location for medical products and Orthocell's products, being small in size and weight with a three-year shelf life, can be distributed at a low cost, making the expansion to new markets both feasible and expedient. Orthocell currently has nine international regulatory approvals and is about to lodge its US FDA application for Remplir in this very large and growing nerve repair market currently worth US\$1.6 billion. I would like to emphasise that the USA nerve repair market



provides the most compelling opportunity in the history of the Company. We remain on schedule to submit the Remplir US 510(k) application in Q4 CY24, with progression into US FDA approval expected US FDA approval in the first quarter of 2025 and sales soon thereafter.

Many years of research and development have now produced a Company on the threshold of a major global breakthrough in revenue. The next 12 months will be pivotal for Orthocell and we believe it will be the most exciting year of development since the Company's first international regulatory approval, received in January 2021. Our first international employees have commenced in the USA and the preparation work for our USA entry in Q4 2025 is well underway.

Paul and the team have done a great job in continually raising the profile of the Company with institutional investors and the media. I will accompany Paul to the USA in early 2025 where we have arranged to meet international investors, potential USA distributors, our new employees, and selected Media for the planned USA launch.

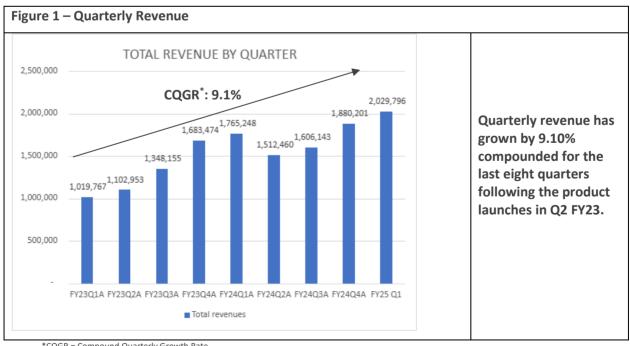
I will now touch on our financial performance.

Financial performance

Orthocell reported increasing quarter on quarter revenue and annual revenue of \$6.76 million in FY24, up 30.8% from the previous year (FY23) of \$5.17 million. This was primarily driven by 55.3% growth in product sales revenue to \$3.01 million in FY24 from \$1.94 million in FY23.

I would like to direct your attention to our growing quarterly revenue, and particularly the compound quarterly growth rate of 9.1% over the previous 8 quarters to Q1 FY25. Sales growth shows clear traction with new and existing surgeons, underpinned by the excellent performance of Striate+ and Remplir in clinical practice.

Paul will discuss the strong performance of our distributors in more detail shortly.



*CQGR = Compound Quarterly Growth Rate



With \$32.8 million in cash and our R&D tax incentive rebate expected prior to the end of the financial year, the Company is now very well positioned to earn interest revenue whilst preparing for a moderate increase to expenses with the USA launch.

The intent is to maximise returns on expense outlay and make sure we expand in appropriate phases and for this purpose we will monitor the revenue to expense ratios. The critical measure to manage is the net cash burn and we do not wish this to increase as we expand into global markets. It is however critical to maximise the revenue opportunities as they develop. The current cash position of \$32.8 million is more than sufficient to bring the Company towards a net positive position.

The total revenue to net expense ratio in FY2022 was 18%, in FY2023 50% and in FY2024 55% and this ratio will increase in line with revenue growth as we build the bridge to a cash flow positive Company.

Orthocell will continue to utilise distributors rather than build its own sales force as we believe this is a more efficient use of capital. The next steps for Orthocell is to maximise revenue from Striate and Remplir whilst maintaining moderate R&D developments in our pipeline of existing innovations.

It is likely that in the 2025 financial year post the successful launch of Remplir in the USA we will then look to expand our pipeline of new products. The executive team will also continue to monitor interest from international companies in partnering on our innovations.

I now invite Paul Anderson to address the AGM.

About Orthocell Ltd

Registered Office - Building 191 Murdoch University, 90 South Street, Murdoch WA 6150 Australia

Orthocell is a regenerative medicine company focused on regenerating mobility for patients by developing products for the repair of a variety of bone and soft tissue injuries. Orthocell's portfolio of products include a platform of collagen medical devices which facilitate tissue reconstruction and healing in a variety of dental and orthopaedic reconstructive applications. Striate+™ was the first product approved for dental GBR applications, is cleared for use in US FDA (510k), Australia (ARTG), New Zealand (WAND), UK (UKCA Mark) and Europe (CE Mark) and is distributed globally by BioHorizons Implant Systems Inc. Remplir™, for peripheral nerve reconstruction, recently received approval and reimbursement in Australia and is distributed exclusively by Device Technologies in the Australian market. SmrtGraft™, for tendon repair, is available in Australia under Special Access Scheme or participation in a clinical trial. The Company's other major products are autologous cell therapies which aim to regenerate damaged tendon and cartilage tissue. Orthocell is accelerating the development of its tendon cell therapy in the US with technology transfer and FDA engagement to confirm the path to the US market and prepare for partnering discussions.

For more information on Orthocell, please visit www.orthocell.com or follow us on Twitter @Orthocell.td and LinkedIn www.linkedin.com/company/orthocell.ltd

Forward Looking Statement

Any statements in this press release about future expectations, plans and prospects for the Company, the Company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate, "expect," "intend," "may," "plan," "predict," "project," "target, "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to successfully develop its product candidates and timely complete its planned clinical programs and the Company's ability to obtain marketing approvals for is product candidates. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.



Managing Director's AGM Presentation

29th November 2024





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It is acknowledged that the Company will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances or unanticipated events occurring after the date of this presentation except as required by law or by any appropriate regulatory authority.



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, NZ and CAN Nerve / Remplir: AUS, NZ and SGP



MANUFACTURED IN AUSTRALIA

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



GROWING RECORD REVENUE

Second consecutive quarter of record revenue, reporting \$2.03m in the September 24 Quarter



>US\$4 Billion p.a. TAM¹

Large, under penetrated markets in bone and nerve repair alone



STRONG BALANCE SHEET, NO DEBT, NO ROYALTIES

Well-funded Company retaining all revenue benefits maximising cashflow



REMPLIR USA APPROVAL 1Q CY25

On track to submit US approval application and commence sales in US\$1.6 billion market

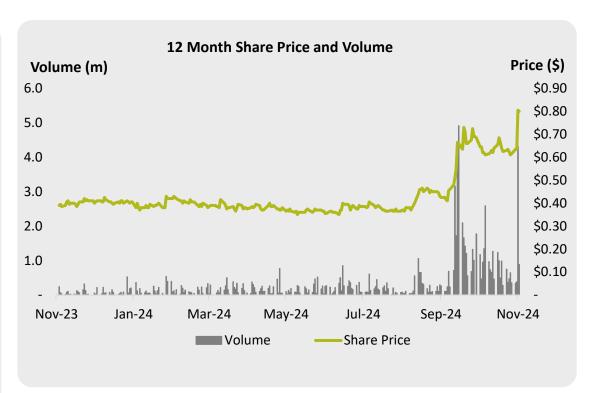
¹ Addressable markets include AUS, USA, EU/UK, SGP, CAN, BRZ, JAP & THA. Referenced papers were used to estimate procedures per annum. Papers used included both US and OUS databases and studies.



Corporate snapshot

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

Share Price (as @ 28 th November)	\$0.81
12 month low/high	\$0.33/\$0.83
Shares outstanding	239M
Market Capitalisation	~\$194M
Cash (31 Oct)	\$32.8M
Debt (31 Oct)	Nil
Substantial Shareholders	%
Founders & Management	~11%
Institutions & HNW's (Sankofa, Regal Funds Mgt, Austral Capital, Thesis Asset Mgt, Frazis Capital, Private Portfolio Mgr's, FundBPO)	~16%

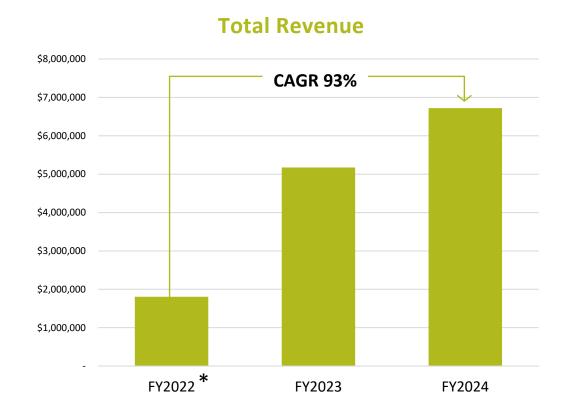






Growing Revenue

FY24 revenue of \$6.76 million, up 30.76% from the previous year (FY23) of \$5.17 million.



^{*} US Striate and AUS Remplir sales commenced in November 2022

Key Highlights

- US Striate+[™] and AUS Remplir[™] product sales commenced in November 2022 and now ahead of expectations
- Quarterly revenue has grown by 9.10% compounded for the last eight quarters following the product launches in November 2022
- Second consecutive quarter of record revenue, reporting \$2.03m in the September 24 Quarter up 7.96% on the \$1.88 million achieved in the June 24 Quarter



Highly Credentialed 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

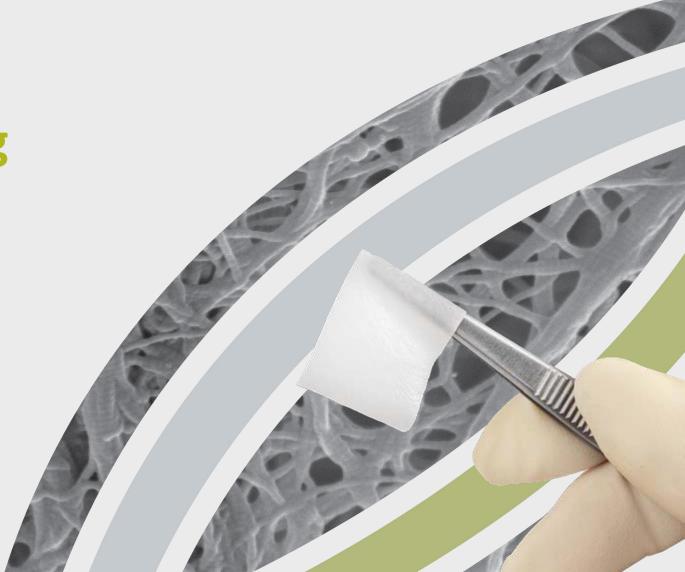
- Unrivalled experience engaging strategic partners in the US highly regarded politician, executive and strategic adviser
- Former Australian US Ambassador and Governor of Western Australia, Deputy Prime Minister, and Minister for both Defence and Finance
- Extensive experience representing both public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



SMRT™ Manufacturing

DEVELOPING AND MANUFACTURING BIOLOGICAL MEDICAL DEVICES





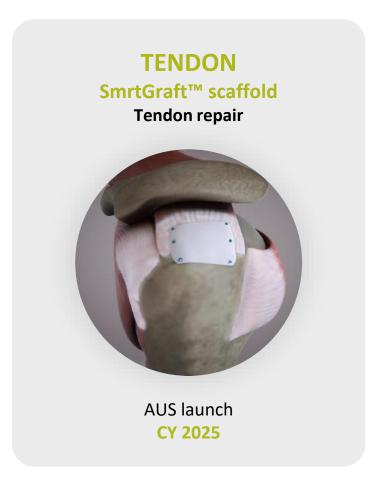


Collagen medical device platform

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







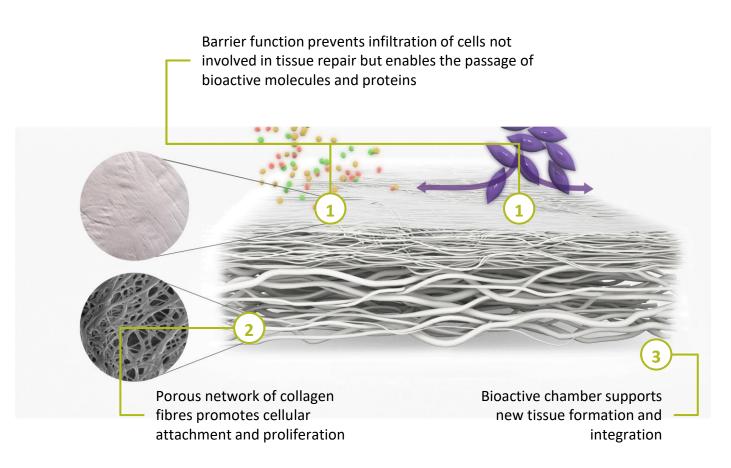


SMRT™ manufacturing

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)









REDEFINING NERVE REPAIR

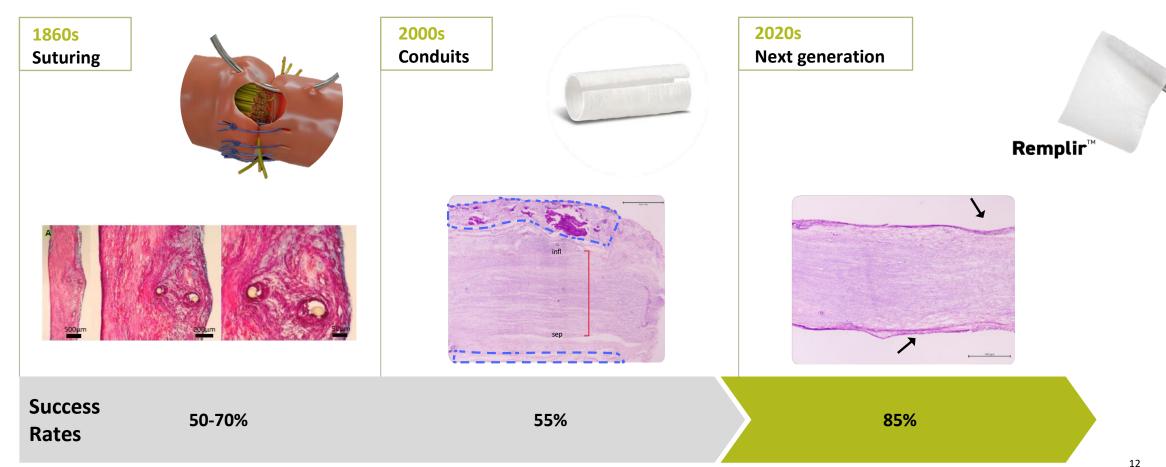






Remplir: Nerve repair breakthrough

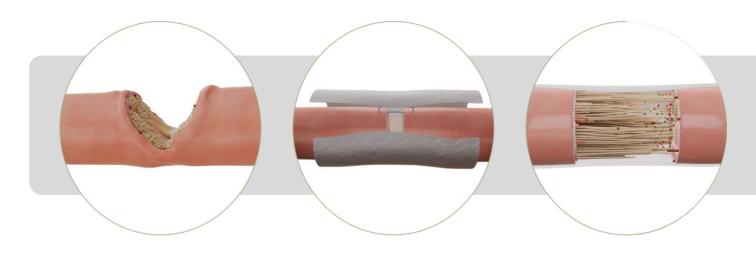
Current repair methods can place delicate nerve tissue under tension, causing scarring, fibrosis and neuroma formation





Remplir: Redefining nerve repair

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



GUIDING PREDICTABLE COUTCOMES IN PERIPHERAL NERVE REPAIR

- Exceptional handling characteristics
- Reducing sutures

- Mimics epineurium (nerve outer layer)
- Returns nerve to pre-injured state



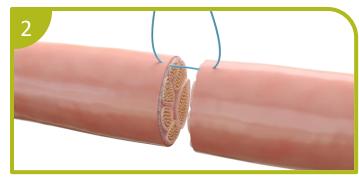


Remplir: surgical technique

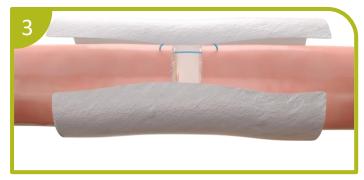
A breakthrough product guiding predictable outcomes in peripheral nerve repair and return of muscle function



Damaged peripheral nerve after traumatic injury to limb



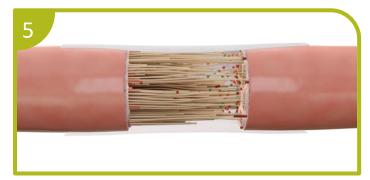
Damaged section of nerve is removed, and ends bought together without tension



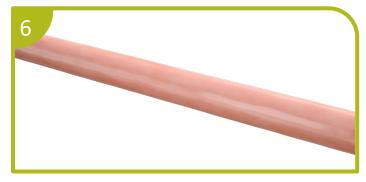
Remplir is wrapped around nerve, reducing suture requirements and facilitating optimal coaptation



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



Remplir creates a protected healing environment allowing new axons to reconnect



Healed nerve restores function to affected limb



Remplir: indications

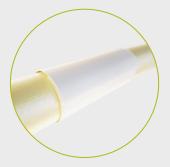
Remplir is the only device that can be used for either connecting severed nerves, protecting damaged nerves or capping amputated nerves





CONNECT

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



PROTECT

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



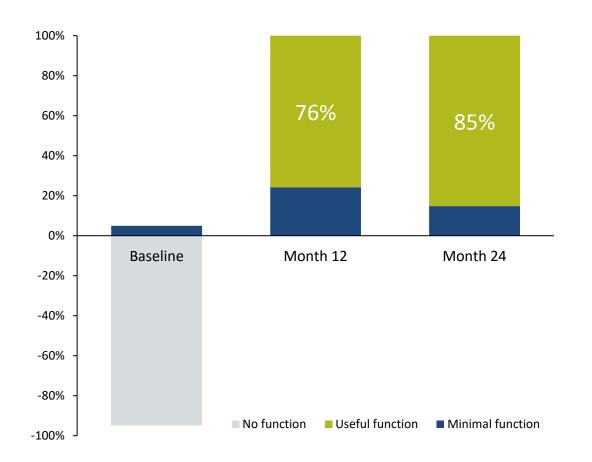
CAP

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



In a single moment, on 5 July 2022, time stopped for Jasmine McGough.

The vibrant 14-year-old from Perth was doing what she loved most, riding her mountain bike on a trail with her family in Margaret River, when she hit a log and fell in a particularly harsh position on her back. She fractured her C5 vertebrae.

Five months after her accident, Jas underwent a nerve transfer procedure with accomplished orthopedic surgeon, Dr Alex O'Beirne. A year on from the procedure, Jas has already reclaimed significant movement and function.

This is her story.

This video is being presented to existing and prospective investors, and potential commercial partners, to provide information about certain therapeutic areas that Orthocell Ltd is focused on.

The video and the matters it describes are not intended for distribution or disclosure beyond Othocell Ltd, its advisors and the current and potential investors and partners participating in the forum in which it is being shown. The video is not intended to promote the use or supply of any of the products that may be featured in the video, but is solely intended to provide information for commercial and investment purposes. It describes a severe case which is not representative of the predominant use of the relevant treatment, although it is within the treatment's intended purpose. The patient in this story will be reimbursed for their time to speak about their experiences.

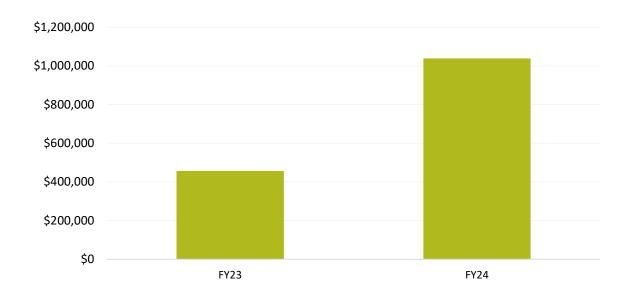




Successful launch with growing revenue

AUS commercial launch¹ 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 exceeding guidance – over 161 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



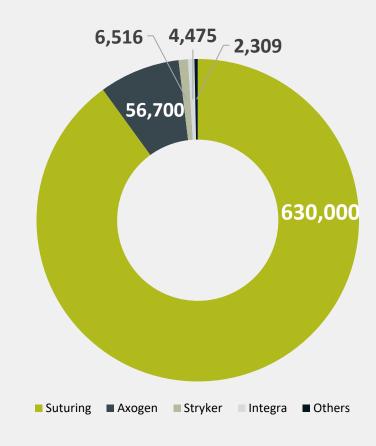
US FDA APPROVAL EXPECTED Q1 CY25 TO US\$1.6 BILLION MARKET



Over 700,000¹ 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)
- Top-line results from Remplir US market authorisation (510k) study on track for December 24
- 510K regulatory application on track for December 24
- Remplir 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



US Sales and Medical Affairs Executives

Orthocell has appointed two experienced US-based executives, John Walker and Phillip Edmondson, to drive the market launch and sales of Remplir following the expected US FDA approval in the first quarter of 2025



John Walker
Vice President – Sales

Mr Walker is a highly experienced sales executive, who has successfully led global product launches and sales strategies, most notably helping to lead the growth of nerve repair device sales at Axogen.



Phillip Edmondson Vice President – Medical Affairs

Mr Edmondson is an award-winning medical affairs professional, who excels in creating product awareness, building advocacy and implementing successful medical education programs that contribute to sales growth.



Remplir: Path to partnering

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

Scale Organisation

- Executive team
- Manufacturing facility
- Quality system
- Third party logistics
- Organisational team
- ERP implementation
- Hire in-country team

US Approval

- Pilot study
- Pre-submission meeting
- Animal surgeries
- In-life assessments
- Data analysis
- 510k submission

Brand Ambassadors

- Scientific narrative
- KOL panel design
- KOL engagement strategy
- In-country collaboration
- Centres of excellence
- Clinician advocacy program

Data Package

- Published preclinical
- Published clinical
- TGA approval
- PMCF
- In country study

Sales and Marketing

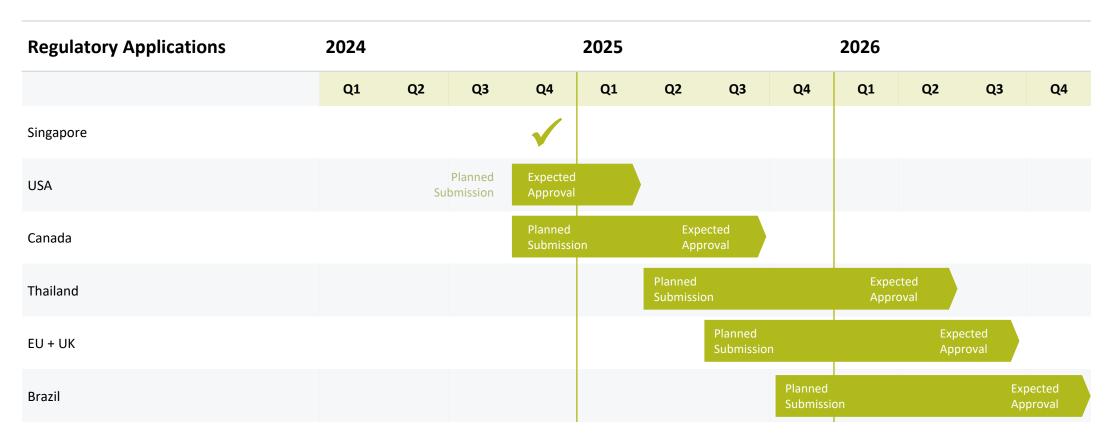
- Positioning strategy
- Pricing strategy
- Customer segmentation
- Promotion plan
- Launch collateral
- Medical education program
- US team training material
- Engage distributors
- Establish key accounts



Remplir: Market Expansion

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

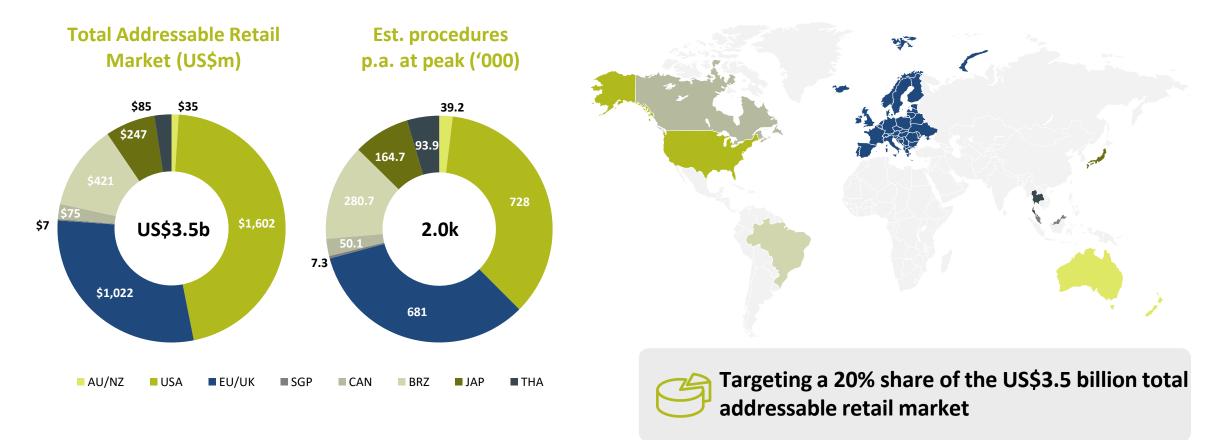
Approved in Australia, New Zealand and Singapore





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 billion¹ per annum











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.



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



Striate+ placed over defect and implant abutment installed



Wound closure



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 Device 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, 2023¹

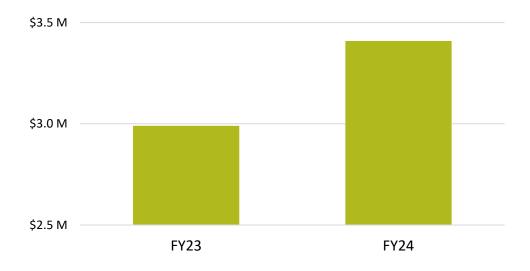




Successful Striate+ launch, revenue growing

US commercial launch¹ of Striate+ dental barrier membrane in November 2022, sales unit volumes now exceeding expectations

Striate+ product sales + license revenue since US market launch



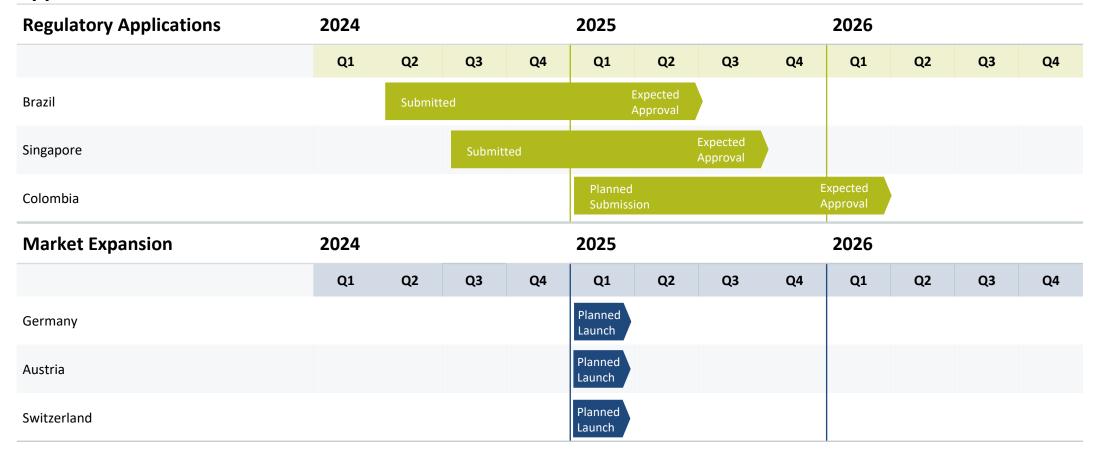
- Gaining excellent traction and growing revenue in US, Europe, UK and Australia, supported by an outstanding 98.6% success rate from the Striate+ dental implant post-marketing clinical study
- 14% growth in Striate+™ revenue from \$2.99M in FY23 to \$3.41M in FY24
- Forecast product sales to BioHorizons 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



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





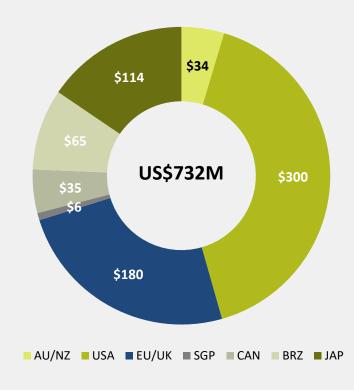
Striate+ revenue growing in US, EU/UK & AUS – and beyond

Significant opportunity to secure 20% share of the US\$732M¹ 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 Southern¹ 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)





Targeting a 20% share of the US\$732M total addressable retail market



Upcoming catalysts¹

Remplir – redefining nerve repair	
Data for US FDA approval	4Q CY24
US FDA submission lodged	4Q CY24
Canada submission lodged	4Q CY24
US FDA market approval	1Q CY25
First sales Singapore	1Q CY25
EU+UK, Thailand & Brazil submissions lodged	2H CY25
Striate+ – growing better bone	
Columbia submission lodged	1Q CY25
Germany, Austria, Switzerland market launch	1Q CY25
Brazil product registration	2Q CY25
Singapore product registration	3Q CY25



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 epicondyle	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



\$32.8M 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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