ortho·cell
advancing tissue repair & regeneration

Quarterly Report – December 2024

15th January 2025: Orthocell Limited (ASX: OCC, "Orthocell" or "the Company") is pleased to release its Quarterly Report for the quarter ended 31 December 2024.

Key highlights for the quarter:

1. **Orthocell's rapid market penetration continued with a third consecutive quarter of record revenue of $2.21 million reported in the December 24 Quarter**
   - Revenue grew by 9% on the previous record of $2.03 million achieved in the September '24 Quarter and is up 46% on the previous corresponding December 23 Quarter, an impressive result given the December Quarter is traditionally seasonally lower
   - Quarterly revenue has now grown by an average of 9%, compounded for the last nine quarters, following Striate+™ USA and Remplir™ AUS product launches in November 2022
   - Sales growth shows clear traction with new and existing surgeons, underpinned by the excellent performance of Striate+ and Remplir in clinical practice, with multiple new markets pending approval which will significantly increase the revenue opportunity moving forward

2. **Global market expansion of Remplir™ continued with the first major international regulatory approval, appointment of an exclusive distributor and achievement of first sales in the key market of Singapore**
   - Regulatory approval was received for Remplir from the Health Sciences Authority (HSA) in Singapore, an important destination for medical treatments in the region and a regulatory gateway to other substantial ASEAN markets
   - Device Technologies Asia were appointed as the exclusive distributor in Singapore, extending a very successful distribution partnership with Device Technologies in Australia and New Zealand, where sales have grown rapidly since launch
   - First Remplir sales were achieved in the Quarter, well ahead of a planned Singapore market launch in Q1 CY25, demonstrating the appetite in this market for quality nerve repair products and the commitment and credentials of the Company's distribution partner

3. **Orthocell submitted its US FDA 510(k) regulatory application for clearance to commercially distribute Remplir into the US$1.6 billion[1] U.S. market, with approval to commence sales expected shortly**
   - The Company successfully completed the 510(k) Regulatory study, meeting all endpoints and providing key data required to support its US FDA 510(k) marketing submission
   - The 510(k) regulatory application for FDA clearance to commercially distribute Remplir into the US$1.6 billion[1] nerve repair market was submitted in December 2024
   - Based on the expected 90 calendar day review process for U.S. FDA 510(k) submissions, and allowing for the festive period closures, Orthocell anticipates market clearance for Remplir in late March or early April 2025

4. **Orthocell is preparing for US commercialisation of Remplir, appointing two key US-based Executives**
   - Orthocell 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 clearance in late March or early April 2025

[1] USA nerve repair market size was estimated using referenced papers from both US and OUS databases and studies.

- Mr Walker is a highly experienced sales executive who has led successful global product launches and sales strategies, most notably leading the growth of nerve repair device sales at Axogen
- 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

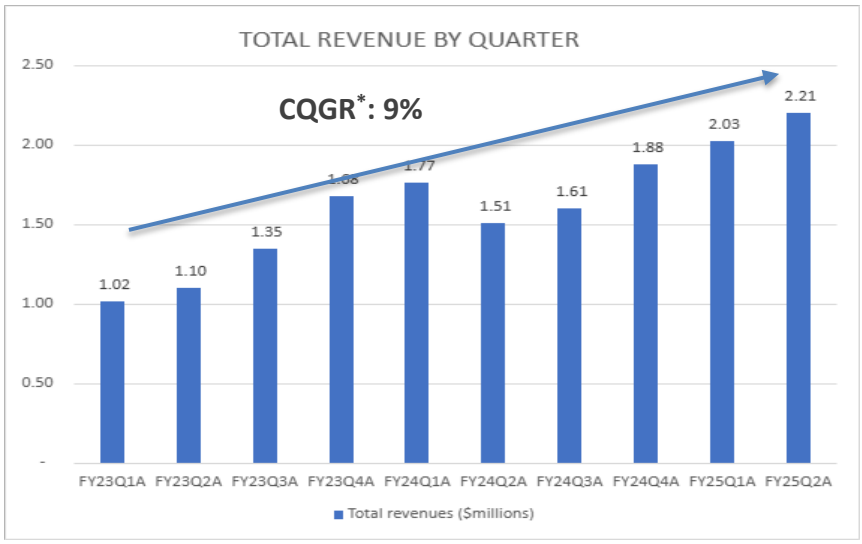
5. **Orthocell completed a $17 million placement at $0.60 to fund US launch of Remplir and drive further growth**
   - The placement received very strong support from existing and new leading Australian and international institutional investors, high net worths and family offices
   - Orthocell remains well funded with ~$31 million in cash at the end of the quarter (and a R+D Grant of over $3 million expected in the March '25 Quarter) to support its global market expansion strategy and beyond the pivotal US product registration for Remplir

Orthocell CEO and MD, Paul Anderson, said: *"It's been another outstanding Quarter for the Company where excellent progress has been made on multiple fronts, highlighted by the achievement of another record revenue quarter and the lodgement of our US FDA submission for approval of Remplir to commence sales in the massive $1.6 billion US market. We look forward to the next Quarter and the year ahead with excitement given the significant potential for exponential revenue growth that the US market can deliver, and believe we are on track to become a key player in the US$4.5 billion global medical device market that we are targeting."*

Corporate and financial commentary

Orthocell reported increasing quarterly revenue to a record of $2.21 million in the December 24 Quarter, up 9% from $2.03 million in the September 24 Quarter and up 46% from $1.51 million for the same period last year (December 23 Quarter, Figure 1). A third consecutive quarter of record revenue shows clear traction with new and existing surgeons, translating to growing sales of the Company's market-leading products Striate+ and Remplir.

Figure 1 – Quarterly Revenue



Quarterly revenue has grown by 9% compounded for the last nine quarters following the product launches in Q2 FY23.

Revenue is up 9% from $2.03 million in September 24 Quarter to $2.21 million in December 24 Quarter.

*CQGR = Compound Quarterly Growth Rate

Cash receipts received from customers, inclusive of GST, for quarter ended 31 December 2024 totalled $1,314k, consistent with the Company's expectations. Net cashflow used in operating activities for the quarter was ($3,620k). Expenditure was focused on commercial and R&D activities.

At the end of the quarter, Orthocell held a cash balance of ~A$31 million. Orthocell's cash balance places the Company in a strong position to continue its strategy to expand into the USA in 2025 and continue lodgement of international regulatory applications. Continued revenue growth from the Australian market with Remplir highlights the best in class product dynamic and the significant revenue potential of global markets.

As detailed in Section 6.1 of Appendix 4C, payments to related parties include salaries, fees and superannuation contributions.

Collagen Medical Devices

Orthocell's collagen medical devices are manufactured using a proprietary SMRT™ manufacturing process, which is designed to remove all cellular and genetic material while preserving the natural collagen structure. The purified collagen scaffold provides the ideal environment for cellular attachment and proliferation. The devices are completely absorbed by the body, integrating and resorbing into the tissue as it heals with no immunogenic reactions. Consequently, this medical device has a wide and growing range of uses in orthopaedics and other surgical specialities. We call this our *collagen medical device platform* - a family of products with wide potential for future development. A facility upgrade to increase manufacturing capacity to >100,000 units per year was completed in December 2022.

Striate+™
more than a barrier membrane

Striate+™ for dental bone and tissue repair

Striate+ is a market-leading resorbable collagen membrane used in guided bone and tissue regeneration procedures. Clinical studies have shown Striate+ supported transition from a two-stage to a single-stage dental procedure, reducing the procedure time and recovery periods by several months. This is of significant interest to patients and clinicians, due to potential improvements in efficiency and efficacy of dental procedures. In July 2022, the Company executed a global exclusive licence and distribution agreement with BioHorizons Implant Systems Inc (**BioHorizons**), one of the largest dental implant companies, for its Striate+ premium dental membrane.

BioHorizon's USA update

Striate+™ continues to impress with momentum building and global market expansion underway

BioHorizons completed a US product launch of Striate+ in November 2022, with a focus on supplying existing Key Opinion Leader (KOL) accounts and other major customers. Since market launch, the BioHorizons marketing and sales team has actively promoted Striate+ at key industry conferences and various educational meetings and workshops. These activities have resulted in a ramp up of product sales and growing revenue in US, Europe, UK and Australia.

Orthocell continues to work with BioHorizons to gain market access in additional large or strategic markets where they have established accounts and/or distribution networks. During the quarter:

1. **BioHorizons progressed its formal Striate+ market launch** plans in the DACH region (Germany/Austria/Switzerland) and remains on track to commence sales in the March 25 Quarter; and
2. **Data showcasing Striate+ clinical performance was presented at the European Association for Osseointegration's 2024 annual congress** to Key Opinion Leaders and dental physicians. The presentation was titled: *Title: "Factors associated with MBL around dental implants using Striate+ collagen membrane in GBR."*

3. **Orthocell's regulatory team progressed its global market expansion program** and remains on track to submit an application for approval in Columbia in Q1 2025 and achieve approvals in the large and strategic markets of Brazil and Singapore by the June 25 Quarter.

Remplir™ for nerve regeneration

Remplir is a collagen nerve wrap used in the repair of peripheral nerve injuries. It provides compression-free protection to the nerve, generating an ideal microenvironment to aid nerve healing. Remplir has proven to be an important step forward in the improvement of nerve repair surgery. Its ease of use, consistent and predictable high-quality outcomes will empower surgeons to improve the lives of people navigating these complex injuries. The Company appointed Device Technologies (DVT) as the exclusive distributor of Remplir across Australia and New Zealand in September 2022 and DVT Asia as exclusive distributor in Singapore in November 2024. Remplir is now being sold in Singapore, Australia and New Zealand, where sales continue to grow with an increasing number of surgeons using and endorsing its unique repair qualities.

Device Technologies - Australia and New Zealand update

Remplir™ accounts expanding and momentum building

DVT officially launched Remplir in Australia in November 2022, with a focus on supplying existing orthopaedic and plastic reconstructive KOL accounts. The ramp up of product sold since market launch is gaining traction with ~160 orthopaedic and plastic surgeons now using Remplir in peripheral nerve repair surgeries, from facial nerves to upper and lower limb nerves, across Australia and New Zealand. Feedback from the clinicians and DVT salesforce continues to be excellent, with adoption driven by Remplir's unique qualities that enable less suturing, creation of the optimal healing microenvironment and facilitation of free gliding within the repair site during the critical healing period.

During the quarter, Orthocell assisted DVT with a series of targeted Remplir education and marketing events, including:

1. **CEO Paul Anderson presented at the annual scientific meeting** of the WA Society of Plastic Surgeons and the inaugural meeting of The Australian Reconstructive Microsurgery Meeting, covering recent advances in nerve repair and highlighting how Remplir's unique qualities assist the surgeon to connect, protect and cap damaged peripheral nerves.
2. **Orthocell was an industry partner and exhibited at the annual New South Wales and Queensland Hand Society Meetings**
3. **A comprehensive customer engagement program** developed by the Company and the DVT team continues to roll out with the completion of numerous, well-received surgeon engagement roadshows across Australia and New Zealand.

Device Technologies Asia Singapore update

First sales ahead of a planned Singapore market launch in Q1 CY25

Singapore is a strategic jurisdiction, both as a preferred destination for sophisticated medical treatments in the region and as a regulatory gateway to other substantial ASEAN markets, in a global nerve repair market estimated to exceed US$3.5 billion[2].

[2] 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.

Commercialisation in Singapore occurred rapidly, with regulatory approval received in October 24 and first sales achieved in December 24. Initial Remplir sales were well ahead of a planned Singapore market launch in Q1 CY25, demonstrating the appetite in this market for quality nerve repair products and the commitment of the Company's distribution partner Device Technologies Asia.

Orthocell is working with DVT Asia to establish key accounts with leading plastic, reconstructive and orthopaedic specialists.

Advanced Cellular Therapies

Orthocell's cell therapies aim to treat diseased or damaged tissue by local implantation or injection of healthy cells where tissue repair is needed. The process involves harvesting a piece of healthy tissue (tendon or cartilage) from the patient. The tissue sample is sent to Orthocell's manufacturing facility where the cells are extracted and grown in culture over a few weeks until there are sufficient cell numbers to implant. Characterisation of the final product is performed to assess the cell's purity, potency and identity before implantation, ensuring high quality tissue repair. The use of a patient's own cells to repair tissue damage reduces the risk of rejection or transmission of infectious diseases. Orthocell is licensed by the TGA to manufacture autologous chondrocytes (OrthoACI™) and tenocytes (OrthoATI™) for cartilage and tendon repair.

OrthoATI™

OrthoATI™ is a world-leading cell therapy in development for the treatment of chronic degenerative tendon injuries. OrthoATI can be used in both surgical and non-surgical applications and is at the forefront of a large and increasing market opportunity, estimated to be worth >US$7.7bn[3] and growing.

During the quarter, the Company attended the Sports Medicine Australia and the Australian College of Sports and Exercise Physicians annual conferences. The meeting was attended by orthopaedic surgeons and sports physicians from across Australasia. Dr Jason Harvey, a respected Australian upper limb specialist surgeon, presented data from the Orthocell-sponsored clinical study comparing OrthoATI to surgery for the treatment of severe, chronic, treatment-resistant lateral epicondylitis ('LE Study').

Orthocell is well-positioned to explore the next stage of development of OrthoATI, targeting US FDA registration, and is working with its US-based corporate adviser to identify potential strategic partners to progress OrthoATI without the need for significant investment in the near term.

Release authorised by:
Paul Anderson
Orthocell Ltd CEO and MD

[3] Addressable market estimate was developed by the Company using reports from US healthcare databases and referenced papers of studies conducted both within and outside the US.

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About Orthocell Limited

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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 CelGro™ 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), Canada (MDL), Australia (ARTG), New Zealand (WAND), the UK (UKCA Mark) and Europe (CE Mark) and is distributed globally by BioHorizons Implant Systems Inc. Remplir™, for peripheral nerve reconstruction, recently received approval in Australia, New Zealand and Singapore and is distributed exclusively by Device Technologies. 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 **@Orthocellltd** 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.

Appendix 4C

Quarterly report for entities subject to Listing Rule 4.7B

Name of entity

Orthocell limited

ABN	**Quarter ended ("current quarter")**
57 118 897 135	31 December 2024

Consolidated statement of cash flows		**Current quarter $A'000s**	**Year to date (6 months) $A'000s**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	1,314	2,452
1.2	Payments for:		
	(a) research & development (including allocated staff costs)	(1,807)	(3,052)
	(b) product manufacturing and operating costs	(919)	(1,725)
	(c) marketing, business development & investor relations	(553)	(1,007)
	(d) leased assets	(1)	(1)
	(e) staff costs (other than R&D staff)	(1,061)	(1,714)
	(f) administration & corporate costs	(692)	(1,190)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	102	603
1.5	Interest & other costs of finance paid	(3)	(5)
1.6	Income taxes paid	-	-
1.7	Government grants & tax incentives received	-	30
1.8	Other	-	-
1.9	**Net cash from / (used in) operating activities**	**(3,620)**	**(5,609)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant & equipment	(29)	(210)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant & equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	**Net cash from (used in) investing activities**	**(29)**	**(210)**

Consolidated statement of cash flows		Current quarter $A'000s	Year to date (6 months) $A'000s
3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	17,000	17,000
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of share options	36	36
3.4	Transaction costs related to issues of equity securities, or convertible notes	(850)	(850)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans & borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (lease payments)	(61)	(133)
3.10	**Net cash from / (used in) financing activities**	**16,125**	**16,053**

4.	**Net increase / (decrease) in cash & cash equivalents for the period**		
4.1	Cash & cash equivalents at beginning of period	18,372	20,614
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,620)	(5,609)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(29)	(210)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	16,125	16,053
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash & cash equivalents at end of period**	**30,848**	**30,848**

5.	**Reconciliation of cash & cash equivalents** at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000s	Previous quarter $A'000s
5.1	Bank balances	3,848	4,372
5.2	Term deposits	27,000	14,000
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	**Cash & cash equivalents at the end of the quarter (should equal item 4.6 above)**	**30,848**	**18,372**

6.	**Payments to related parties of the entity & their associates**	Current quarter $A'000s
6.1	Aggregate amount of payments to these parties included in item 1	364
6.2	Aggregate amount of payments to these parties included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

7	**Financing facilities available** *Note: the term 'facilty' includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the position.*	Total facility amount at quarter end $A'000s	Amount drawn at quarter end $A'000s
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	-	-

7.5	**Unused financing facilites available at quarter end**	-

7.6 Include in the box below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

8.	**Estimated cash available for future operating activities**	**$A'000s**
8.1	Net cash from / (used in) operating activities (item 1.9)	(3,620)
8.2	Cash and cash equivalents at quarter end (item 4.6)	30,848
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	30,848
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**9**

Note: if the entity has reported positive net operating cash flows in item 1.9 answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

1. Does the entity expect that it will continue to have the current level of net operating cash flows for the time being

   Answer: N/A

2. Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful.

   Answer: N/A

3. Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

   Answer: N/A

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 15 January 2025

Authorised by: Paul Anderson - Managing Director
(Name of body or officer authorising release - see note 4)

Notes

1 This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2 If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, AASB 107: Statement of Cash Flows apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3 Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4 If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5 If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's Corporate Governance Principles and Recommendations, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.