ortho·cell
advancing tissue repair & regeneration

# Quarterly Report – September 2024

**17th October 2024:** Orthocell Limited (ASX: OCC, "Orthocell" or "the Company") is pleased to release its Quarterly Report for the quarter ended 30 September 2024.

**Key highlights for the quarter:**

1. **Orthocell achieved a second consecutive quarter of record revenue, reporting $2.03m in the September 24 Quarter**
   - Revenue grew by 7.96% on the $1.88 million achieved in the June 24 Quarter
   - Quarterly revenue has grown by an average of 9.10%, compounded for the last eight 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.

2. **Orthocell received first major international regulatory approval for Remplir in the key market of Singapore**
   - Regulatory approval received from the Health Sciences Authority (HSA) in Singapore for its market-leading nerve repair product, Remplir
   - Singapore is a strategic regulatory jurisdiction, both as an important destination for medical treatment in the region and as a regulatory gateway to other substantial ASEAN markets
   - Orthocell is in advanced discussions with an experienced international medical device distributor ahead of the Singapore market launch and first sales anticipated for Q1 CY25.

3. **Global market expansion of Striate+ continues with regulatory approval and first sales in Canada**
   - Orthocell's exclusive global distribution partner BioHorizons recorded first sales of Striate+ in the key market of Canada, after receiving regulatory approval only 2 months earlier in July
   - Striate+, for use in dental guided bone and tissue regeneration, is 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-market clinical study and BioHorizon's established network of distributors and customers.

4. **Orthocell accelerates market expansion of Striate+ and Remplir with further regulatory applications submitted and planned**
   - With Striate+ gaining traction with surgeons in the US, Europe/UK and Australia and recently approved in Canada, the Company is accelerating market access into Brazil and Singapore with regulatory approval anticipated within 6-12 months. Further applications are planned.
   - With Remplir gaining traction with surgeons in Australia, regulatory clearance achieved in Singapore and the USA anticipated in Q1 2025, the Company is accelerating market access into other new markets with a further three applications in Canada, Thailand and EU/UK planned in the next 6-12 months.

5. **Top-line results from Remplir US market authorisation study expected in Q4 CY24**
   - Orthocell remains on schedule to submit its US 510(K) market authorisation application in Q4 CY24 and progression into US FDA Approval and then sales soon thereafter.

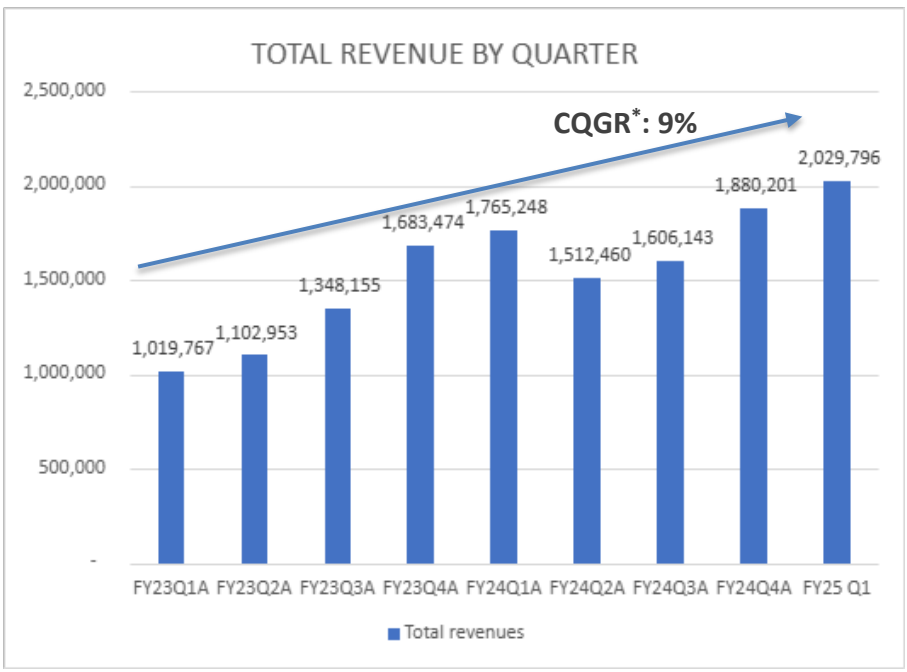
6. **Strong balance sheet with $18.4 million cash at bank at the end of the quarter**
   - Orthocell remains well funded with $18.4million in cash to support its global market expansion strategy and beyond the pivotal US product registration for Remplir

**Orthocell CEO and MD, Paul Anderson, said:** *"*This is another outstanding Quarter for the Company on a number of fronts and we are delighted with the continued growth in demand and record quarterly revenue for our market-leading products Striate+ and Remplir. These sales results demonstrate increasing market traction, which is driven by the consistent and predictable outcomes surgeons can achieve using our products. We are excited by the potential for exponential growth and believe we are on track to become a key player in a US$4 billion global market.*"*

## Corporate and financial commentary

Orthocell reported increasing quarterly revenue to a record of $2.03 million in the September 24 Quarter, up 7.96% from $1.88 million in the June 24 Quarter and up 14.99% from $1.76 million for the same period last year (September 23 Quarter). A second 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 9.10% compounded for the last eight quarters following the product launches in Q2 FY23.**

**Revenue is up 7.96% from $1.88 million in June 24 Quarter to $2.03 million in September 24 Quarter.**

*CQGR = Compound Quarterly Growth Rate

Cash receipts received from customers, inclusive of GST, for quarter ended 30 September 2024 were $1,139k, consistent with the Company's expectations. Net cashflow from operating activities for the quarter was ($1,989k). Expenditure was focused on commercial and R&D activities.

At the end of the quarter, Orthocell held a cash balance of A$18.4m. 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 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+™ 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. **Following regulatory approval in Canada** in early July, BioHorizons recorded a fast transition to first sales of Striate+ in this key market,
2. **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
3. **Orthocell's regulatory team progressed its global market expansion program** and remains on track to 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 is proving 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 has been working with DVT to establish key accounts with leading plastic, reconstructive and orthopaedic specialists in Australia and New Zealand.

**Device Technologies (DVT) 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 **~150 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 very encouraging, 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. **The 2nd Annual Nerve Transfer and Reconstruction Symposium** was attended by a diverse group of surgeons from across Australia and featured a faculty of internationally recognised experts, including keynote speaker Dr. Tom Quick from the United Kingdom. The scientific meeting was a resounding success, with a comprehensive program of presentations, discussions and hands-on workshops aimed at advancing the understanding and application of cutting-edge nerve repair techniques.
2. **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 in NSW, VIC, TAS, QLD, WA and NZ.
3. **Presentation at the NZ Society for Surgery of the Hand Meeting** by Orthocell's inventor and Chief Scientific officer, Professor Ming Hao Zheng. Professor Zheng covered recent advances in nerve repair, highlighting how Remplir's unique qualities assist the surgeon to connect, protect and cap damaged peripheral nerves.

**Remplir™ US market authorisation study on track**

Orthocell reported successful completion of all nerve repair surgeries in the Remplir US market authorisation study. The Company has progressed to the final two stages of the study and top-line results are on track to be announced in Q4 CY24. Completion of the study will be followed by its US 510(K) market authorisation application and progression into sales soon thereafter.

## 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™
for regeneration of human tendon

## 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[1] and growing.

During the quarter, the Company attended the 52nd AOA WA Branch Annual Scientific Meeting. The meeting was attended by orthopaedic and plastic reconstructive surgeons from across Western Australia. Dr Allan Wang, an Australian leading shoulder and upper limb specialist surgeon, presented on the recent 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 the product for 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

For more information, please contact:

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[1] 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.

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 and reimbursement in Australia and New Zealand 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 | 30 September 2024 |

| **Consolidated statement of cash flows** | | **Current quarter $A'000s** | **Year to date (3 months) $A'000s** |
|---|---|---|---|
| **1.** | **Cash flows from operating activities** | | |
| 1.1 | Receipts from customers | 1,139 | 1,139 |
| 1.2 | Payments for: | | |
| | (a) research & development (including allocated staff costs) | (1,245) | (1,245) |
| | (b) product manufacturing and operating costs | (805) | (805) |
| | (c) marketing, business development & investor relations | (454) | (454) |
| | (d) leased assets | (1) | (1) |
| | (e) staff costs (other than R&D staff) | (653) | (653) |
| | (f) administration & corporate costs | (498) | (498) |
| 1.3 | Dividends received (see note 3) | - | - |
| 1.4 | Interest received | 500 | 500 |
| 1.5 | Interest & other costs of finance paid | (2) | (2) |
| 1.6 | Income taxes paid | - | - |
| 1.7 | Government grants & tax incentives received | 30 | 30 |
| 1.8 | Other | - | - |
| **1.9** | **Net cash from / (used in) operating activities** | **(1,989)** | **(1,989)** |

| | | | |
|---|---|---|---|
| **2.** | **Cash flows from investing activities** | | |
| 2.1 | Payments to acquire: | | |
| | (a) entities | - | - |
| | (b) businesses | - | - |
| | (c) property, plant & equipment | (180) | (180) |
| | (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** | **(180)** | **(180)** |

| Consolidated statement of cash flows | | Current quarter $A'000s | Year to date (3 months) $A'000s |
|---|---|---|---|
| **3.** | **Cash flows from financing activities** | | |
| 3.1 | Proceeds from issues of equity securities (excluding convertible debt securities) | - | - |
| 3.2 | Proceeds from issue of convertible debt securities | - | - |
| 3.3 | Proceeds from exercise of share options | - | - |
| 3.4 | Transaction costs related to issues of equity securities, or convertible notes | - | |
| 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) | (73) | (73) |
| **3.10** | **Net cash from / (used in) financing activities** | **(73)** | **(73)** |

| **4.** | **Net increase / (decrease) in cash & cash equivalents for the period** | | |
|---|---|---|---|
| 4.1 | Cash & cash equivalents at beginning of period | 20,614 | 20,614 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (1,989) | (1,989) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above) | (180) | (180) |
| 4.4 | Net cash from / (used in) financing activities (item 3.10 above) | (73) | (73) |
| 4.5 | Effect of movement in exchange rates on cash held | - | - |
| **4.6** | **Cash & cash equivalents at end of period** | **18,372** | **18,372** |

| **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 | 1,372 | 3,114 |
| 5.2 | Term deposits | 17,000 | 17,500 |
| 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)** | **18,372** | **20,614** |

| **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 | 409 |
| 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) | (1,989) |
| 8.2 | Cash and cash equivalents at quarter end (item 4.6) | 18,372 |
| 8.3 | Unused finance facilities available at quarter end (item 7.5) | - |
| 8.4 | Total available funding (item 8.2 + item 8.3) | 18,372 |
| 8.5 | **Estimated quarters of funding available (item 8.4 divided by item 8.1)** | **9.24** |

*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: 17 October 2024

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.