

Quarterly Report – March 2024

8th April 2024: Orthocell Limited (ASX: OCC, “Orthocell” or “the Company”) is pleased to release its Quarterly Report for the quarter ended 31 March 2024.

Key highlights for the quarter:

- 1. Orthocell reports increasing revenue of \$1.61 million in Q3 FY24, up 19% from \$1.35 million for the same period last year.**
 - Increasing revenue driven by growth in new product sales. Year to date revenue of \$4.88 million is up 40.7% from \$3.47 million for the same period last year.
 - Quarterly revenue has grown, on average, by 8% compounded for the last six quarters, following Striate+™ US and Remplir™ AUS product launches in November 2022.
- 2. Successful completion of a \$3.5 million strategic placement**
 - Orthocell strengthened its financial position and share register completing a \$3.5 million strategic placement to prominent investors including Mr Chris Ellison, Mr Rod Jones, Mr Michael Malone, the McCusker Family and the Merchant Biotech Fund.
- 3. Strong balance sheet with \$20.1m cash at bank at the end of the quarter**
 - With existing cash of \$20.1 million and the pending R&D Tax rebate of circa \$3.0 million, the Company is very well funded for its global market expansion strategy and well beyond the pivotal US product registration for Remplir™ expected in Q1 CY25.
- 4. Strengthening the Board with appointment of the Hon Kim Beazley AC**
 - Orthocell continued to execute its Board renewal program with the appointment of the Hon Kim Beazley AC, former Australian US Ambassador and Governor of Western Australia, Deputy Prime Minister, and Minister for both Defence and Finance, as an Independent Non-Executive Director to the Board.
 - The Board is now majority independent with four Non-Executive Directors (John Van Der Wielen, Dr Ravi Thadhani, Professor Fiona Wood AM and the Hon Kim Beazley AC) and one Executive Director (Mr Paul Anderson).
- 5. Successful completion of all nerve repair surgeries in Remplir™ US market authorisation study**
 - All surgical repairs of severed nerves were performed with no adverse events. This provides further confidence that the safety and effectiveness outcomes will be consistent with the pilot study and positions the Company for US approval in 1Q CY25.
 - Top-line results from this study are expected in Q3 CY24, and Orthocell remains on schedule to submit its US 510(K) market authorisation application in Q4 CY24 and progression into sales soon thereafter.
- 6. Orthocell submitted its Singapore Regulatory Application for Remplir™ in February 2024**
 - Orthocell’s global expansion strategy for its market leading peripheral nerve repair product Remplir, continues to build with the submission of its regulatory application to the Health Services Authority of Singapore for approval to market and sell the Product.

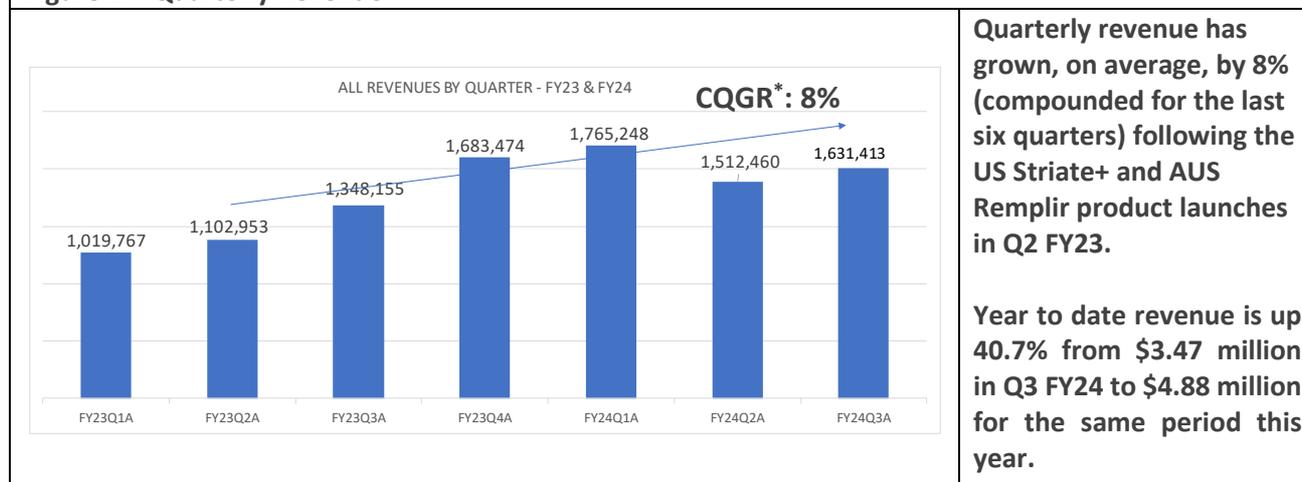


Orthocell Managing Director, Paul Anderson, said: “Orthocell has completed a very solid quarter, growing revenues whilst strengthening the balance sheet and share register. I am very pleased with the performance of our distribution partners and the continued increase in product adoption. With a highly respected and experienced Board now in place, we are in a strong position to continue to gain commercial traction and drive Remplir, our breakthrough nerve repair device, into global markets.”

Corporate and financial commentary

Revenue for Q3 FY24 increased to \$1.61 million compared to \$1.51 million for the prior quarter, up 19% for the same quarter last year of \$1.35 million. This was driven by a 34% growth in new product sales and underpinned by our consistent contract revenue from the exclusive distribution deal with BioHorizons.

Figure 1 – Quarterly Revenue



*CQGR = Compound Quarterly Growth Rate

Cash receipts received from customers, inclusive of GST, for quarter ended 31 March 2024 were \$645k. This is in line with the Company’s expectations. Net cash used in operating activities for the quarter was \$2.6m. Expenditure focused on commercial and R&D related activities.

At the end of the quarter, Orthocell held a cash balance of A\$20.06m. Orthocell’s cash balance places the Company in a strong position to continue its strategy to expand into the USA in 2025 and continue its lodgement of international regulatory applications. Continued penetration of the Australian market with Remplir continues to highlight 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.

CelGro™ Platform Medical Device

CelGro™ is a biological collagen membrane manufactured by Orthocell to augment surgical repair of bone and soft tissue. CelGro represents a breakthrough in bone and soft tissue reconstruction and offers significant commercial potential in existing addressable markets of bone, nerve, tendon and cartilage, as well as wider applications in general surgical and soft tissue reconstructive applications. CelGro medical devices, including Striate+ and Remplir are manufactured by Orthocell at its quality-controlled facility in WA, using the



Company's proprietary SMRT™ manufacturing technology. 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 update – Striate continues to impress

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. This has resulted in a successful ramp up of product sold and continues to build momentum. During the quarter, the Company received further positive feedback regarding the products performance, with uptake driven by the surgeons' preference for a high-quality dental membrane that is easier to use and facilitates better patient outcomes.

PerFORM builds momentum

In September 2023, Ace Southern successfully launched a private label called "PerFORM collagen membrane" (Striate+ product branded as Perform). Ace Southern is a subsidiary of Henry Schein with established networks of US based dental service organisations (DSO's) that provide consumables to multiple dental practices. The Company completed another shipment of PerFORM during the quarter to meet the initial demand of key customers. Adding Ace Southern to the list of US distributors, will increase the representation of the product and assist in servicing a wide range of dental customers in the US.

BioHorizons Camlog officially launches Striate+ in the EU/UK

BioHorizons Camlog recently announced (Q2 FY24) the official launch of Striate+, for use in guided bone and tissue regeneration in the EU. Product adoption is gaining traction with the Company completing substantial shipments of Striate during the quarter to meet the initial demand of key customers.

BioHorizons Camlog is a wholly owned subsidiary of BioHorizons headquartered in Basel, Switzerland. BioHorizons Camlog is now actively promoting the use of Striate+ in the EU stating that the "product strengthens its position as a global provider of regenerative solutions for implant dentistry, meeting the needs of a large portion of clinicians currently looking to improve the outcomes of their surgical procedures. Striate+ is now exclusively available for ordering through BioHorizons Camlog in Belgium, France, Ireland, Italy, Netherlands, Portugal, Spain and UK. For further information about Striate+ please visit <https://www.biohorizons.com/Products/StriatePlus>."



Remplir™
nerve wrap

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, which are achieved in a shorter timeframe compared to other methods, 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

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 in the ~18 months since market launch is gaining traction with **100+ orthopaedic and plastic surgeons now using Remplir in peripheral nerve repair surgeries, from facial to upper and lower limb nerves, across Australia and New Zealand**. Feedback from the DVT salesforce has been 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.

The DVT team is executing a comprehensive customer engagement program designed to continue momentum in product adoption and to grow the establishment of new orthopaedic and plastic reconstructive accounts. During the quarter, Orthocell assisted DVT with a series of targeted Remplir education and training events, including surgeon engagement roadshows, congress attendance and other scientific meetings in NZ, NSW, VIC, TAS, QLD and WA.

The Company also recently attended the American Society for Peripheral Nerve and the American Academy of Orthopaedic Surgeons 2024 annual meetings. The scientific and industry meetings provided an opportunity to continue the US KOL engagement program, a critical part of the US market access strategy.

Successful completion of all Nerve Repair Surgeries in Remplir™ US Market Authorisation Study

On 25 March 2024, Orthocell announced it had successfully completed the first stage of the Remplir US 510(k) market authorisation nerve repair study. All surgical repairs of severed nerves were performed with no adverse events reported. Completion of the first stage enables the Company to progress with the final two stages of the study and provides further confidence that the safety and effectiveness outcomes will be consistent with the pilot study.

Top-line results from this study are expected in Q3 CY24, and Orthocell remains on schedule to submit its US 510(K) market authorisation in Q4 CY24 and progression into sales soon thereafter.

Advanced Cellular Therapies

Orthocell cell therapies harvest autologous cells from the same tissue that requires repair. A piece of healthy tissue is collected by a surgeon and transported to the Orthocell laboratory. The cells are grown in the laboratory over a few weeks until there is enough to implant. Cells are assessed for purity, potency and identity before being returned to the patient, ensuring high quality tissue repair.

During the quarter, the Company completed a scheduled replacement of the Heating, Ventilation and Air Conditioning (HVAC) system supplying the cell therapy manufacturing clean rooms. Clean rooms were shut down over December 2023 and re-commissioned in early February 2024.



OrthoATI™
for regeneration of human tendon

OrthoATI™

OrthoATI is a world-leading cell therapy in development for the treatment of chronic degenerative tendon injuries (tendinopathy/tendonitis). 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\$7.7bn¹ and growing.

Recently Orthocell announced results from its clinical study comparing OrthoATI to surgery for the treatment of severe, chronic, treatment-resistant lateral epicondylitis ('LE Study'). The data confirmed that the study met its primary endpoint, demonstrating that OrthoATI is as effective as surgery in the treatment of lateral epicondylitis. With this successful study in lateral epicondylitis completed, Orthocell is now well positioned to engage partners to explore the next stage of development of the product for US FDA registration. The Company is looking to secure a US based corporate adviser to assist the Company in engaging a strategic partner to progress OrthoATI without the need for significant investment in the near term.

Release authorised by:

Paul Anderson
Managing Director, Orthocell Ltd

For more information, please contact:

General & Investor enquiries

Paul Anderson

Orthocell Limited
Managing Director

P: +61 8 9360 2888

E: paulanderson@orthocell.com.au

Media enquiries

Haley Chartres

HACK Director

P: +61 423 139 163

E: haley@hck.digital

About Orthocell Limited

ACN 118 897 135

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 CelGro™, a collagen medical device which facilitates 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) 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, manufacturing scale up and FDA engagement in advance of a randomised controlled study under FDA supervision.

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.



For more information on Orthocell, please visit www.orthocell.com or follow us on Twitter [@OrthocellLtd](https://twitter.com/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 its 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

57 118 897 135

Quarter ended ("current quarter")

31 March 2024

Consolidated statement of cash flows	Current quarter \$A'000s	Year to date (9 months) \$A'000s
1. Cash flows from operating activities		
1.1 Receipts from customers	645	2,438
1.2 Payments for:		
(a) research & development (including allocated staff costs)	(1,684)	(5,691)
(b) product manufacturing and operating costs	(369)	(1,513)
(c) marketing, business development & investor relations	(365)	(992)
(d) leased assets	(1)	(2)
(e) staff costs (other than R&D staff)	(416)	(1,085)
(f) administration & corporate costs	(520)	(1,018)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	136	597
1.5 Interest & other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants & tax incentives received	-	-
1.8 Other	-	-
1.9 Net cash from / (used in) operating activities	(2,574)	(7,266)
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant & equipment	(302)	(772)
(d) investments	-	-
(e) intellectual property	(9)	(16)
(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	(311)	(788)

Consolidated statement of cash flows	Current quarter \$A'000s	Year to date (9 months) \$A'000s
3. Cash flows from financing activities		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	3,500	3,591
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	(123)	(123)
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)	(49)	(165)
3.10 Net cash from / (used in) financing activities	3,328	3,303

4. Net increase / (decrease) in cash & cash equivalents for the period		
4.1 Cash & cash equivalents at beginning of period	19,624	24,818
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(2,574)	(7,266)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(311)	(788)
4.4 Net cash from / (used in) financing activities (item 3.10 above)	3,328	3,303
4.5 Effect of movement in exchange rates on cash held	-	-
4.6 Cash & cash equivalents at end of period	20,067	20,067

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	3,067	3,624
5.2 Term deposits	17,000	16,000
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)	20,067	19,624

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	461
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	Total facility amount at quarter end \$A'000s	Amount drawn at quarter end \$A'000s
<i>Note: the term 'facility' includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the position.</i>		
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 Total financing facilities	-	-

7.5 Unused financing facilities available at quarter end	-
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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)	(2,574)
8.2 Cash and cash equivalents at quarter end (item 4.6)	20,067
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	20,067
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	7.8

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:

- 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

- 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

- 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

- This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- This statement gives a true and fair view of the matters disclosed.

Date: 8 April 2024

Authorised by: Paul Anderson - Managing Director

(Name of body or officer authorising release - see note 4)

Notes

- 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.
- 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.
- 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.
- 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".
- 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.