ortho·cell
advancing tissue repair & regeneration

Quarterly Report – June 2024

16th July 2024: Orthocell Limited (ASX: OCC, "Orthocell" or "the Company") is pleased to release its Quarterly Report for the quarter ended 30 June 2024.

Key highlights for the quarter:

1. **Orthocell reports record quarterly revenue of $1.84 million and year-on-year growth of 30% to $6.72 million**

   - Increasing quarterly revenue of $1.84 million in Q4 FY24, up 14.41% from $1.61 million in Q3 FY24 and up 9.2% from $1.68 million for the same period last year (Q4 FY23).
   - FY24 revenue of $6.72 million, up 30.4% from the previous year (FY23) of $5.15 million.
   - Quarterly revenue has grown on average by 9% compounded for the last seven quarters, following Striate+™ US and Remplir™ AUS product launches in November 2022.

2. **Strong balance sheet with $20.60 million cash at bank at the end of the quarter**

   - Orthocell received $3.05 million R&D tax incentive refund during the quarter and remains well funded for its global expansion strategy and beyond its major US product registration for Remplir, expected in Q1 CY25.

3. **OCC to launch third revenue generating product in SmrtGraft™ for tendon repair**

   - Orthocell submitted an application to the Therapeutic Goods Administration (TGA) for Australian market approval of its SmrtGraft™ tendon repair device. This application introduces Orthocell to the Tendon, repair and regeneration market.

4. **Compelling 85% success rates from Remplir™ nerve repair study published in peer-reviewed clinical journal**

   - Compelling outcomes, now published in peer-reviewed Journal of Reconstructive Microsurgery Open, confirm Orthocell's nerve repair product, Remplir, as the ideal medical device for connecting severed nerves, protecting damaged nerves or capping amputated nerves.

5. **Outstanding 98.6% success rate from Striate+™ dental implant post-market clinical study**

   - Post-market clinical study results demonstrated that dental implant treatment with guided bone regeneration using Orthocell's Striate+ dental membrane resulted in an outstanding 98.6% success rate. This compelling real-world evidence confirms Orthocell's dental membrane product, Striate+, as the optimal medical device for all types of guided bone regeneration and dental implant procedures.

6. **Top-line results from Remplir™ US market authorisation study expected in Q4 CY24**

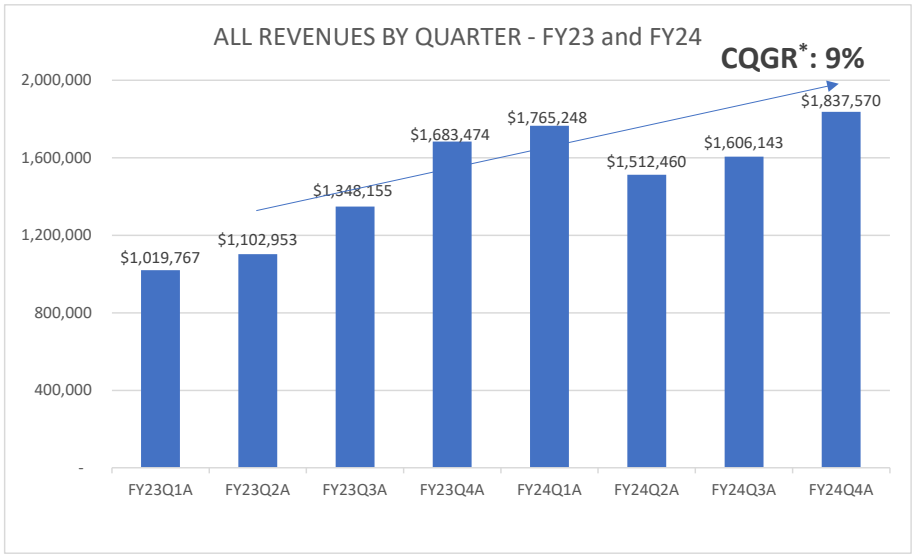
   - Orthocell remains on schedule to submit its US 510(K) market authorisation application in Q4 CY24 and progression into sales soon thereafter.

Orthocell Managing Director, Paul Anderson, said: *"Orthocell has completed a record quarter with increasing revenues and strengthening the balance sheet. I am delighted with the performance of our distribution partners and the continued increase in product adoption. With a highly respected and experienced Board in place, we are in a strong position to continue to gain commercial traction and drive our innovative products into global markets."*

Corporate and financial commentary

Increasing quarterly revenue of $1.84 million in Q4 FY24, up 14.41% from $1.61 million in Q3 FY24 and up 9.2% from $1.68 million for the same period last year (Q4 FY23). This was driven by continued growth in new product sales and our consistent contract revenue from BioHorizons.

Figure 1 – Quarterly Revenue



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

Revenue is up 30.40% from $5.15 million in FY23 to $6.72 million in FY24.

*CQGR = Compound Quarterly Growth Rate

Cash receipts received from customers, inclusive of GST, for quarter ended 30 June 2024 were $976k. This is in line with the Company's expectations. Net cash inflow from operating activities for the quarter was $790k. Expenditure focused on commercial and R&D related activities.

At the end of the quarter, Orthocell held a cash balance of A$20.60m. 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 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

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 which is continuing to build momentum. During the quarter, the Company received further positive feedback regarding the product's performance at the annual CH3 Key Opinion Leader conference. The conference was attended by over 120 dental surgeons widely regarded as global Key Opinion Leaders in dental surgery from the USA, EU/UK and South America. Numerous surgeons commented on Striate+'s superior handling qualities and consistent and predictable quality of newly formed bone when using Striate+ during dental implant procedures.

BioHorizons Camlog EU/UK update – gaining traction and expanding into other key jurisdictions

BioHorizons Camlog is gaining traction in Striate+ sales since the recent official launch of Striate+ in Belgium, France, Ireland, Italy, Netherlands, Portugal, Spain and United Kingdom.

BioHorizons Camlog is a wholly owned subsidiary of BioHorizons headquartered in Basel, Switzerland. BioHorizons Camlog is 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. For further information about Striate+ please visit https://www.biohorizons.com/Products/StriatePlus."

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 in the ~18 months since market launch is gaining traction with **120+ 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.

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, SA and WA.

The Company also recently attended the 2024 3rd combined meeting of the American Society for Surgery of the Hand and the Australian Hand Surgery Society. These scientific and industry meetings were attended by ~250 orthopaedic and plastic reconstructive surgeons from Australia and the USA. The meetings provided an opportunity to continue the Australian medical education program and advance engagement of US Key Opinion Leaders. Orthocell hosted an industry forum designed to highlight the role of Remplir in nerve repair. The forum was titled, "Providing a conduit for nature – redefining nerve repair" with three key sessions completed by Australian and USA Key Opinion Leaders:

1. Dr David Brogan, USA Hand and Wrist Surgeon and Remplir KOL - "Biological principles of nerve repair and nerve transfer"
2. Dr Alex O'Beirne, Australian Orthopaedic Surgeon and KOL – "Clinical outcomes of nerve transfer using an epineurial substitute device"
3. Professor Ming Hao Zheng, Remplir inventor and Orthocell's CSO – "Histological assessment of nerve device and sutures on peripheral nerve repair"

Remplir™ US market authorisation study update

Orthocell recently reported successful completion of all nerve repair surgeries in the Remplir US market authorisation study. 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 Q4 CY24, and Orthocell remains on schedule to submit its US 510(K) market authorisation application in Q4 CY24 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™

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$7.7bn[1] and growing.

During the quarter, the Company attended the 2024 3rd combined meeting of the American Society for Surgery of the Hand and the Australian Hand Surgery Society. The scientific and industry meetings were attended by ~250 orthopaedic and plastic reconstructive surgeons from Australia and the USA. The meetings provided an opportunity to continue the US strategic partnering program. At the meeting Dr Jason Harvey, an Australian leading hand, wrist and elbow surgeon presented on the recent clinical study comparing OrthoATI to surgery for the treatment of severe, chronic, treatment-resistant lateral epicondylitis ('LE Study'). The presentation was titled, "Randomised Controlled Study of Autologous Tendon-Cell Injection Versus Surgery for Treatment of Severe Chronic Treatment-Resistant Lateral Epicondylitis."

Orthocell is now 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:
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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 June 2024

Consolidated statement of cash flows		**Current quarter $A'000s**	**Year to date (12 months) $A'000s**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	976	3,414
1.2	Payments for:		
	(a) research & development (including allocated staff costs)	(1,773)	(7,759)
	(b) product manufacturing and operating costs	(549)	(1,800)
	(c) marketing, business development & investor relations	(247)	(1,248)
	(d) leased assets	(1)	(3)
	(e) staff costs (other than R&D staff)	(414)	(1,403)
	(f) administration & corporate costs	(468)	(1,578)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	217	814
1.5	Interest & other costs of finance paid	(2)	(2)
1.6	Income taxes paid	-	-
1.7	Government grants & tax incentives received	3,051	3,051
1.8	Other	-	-
1.9	**Net cash from / (used in) operating activities**	**790**	**(6,514)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant & equipment	(194)	(923)
	(d) investments	-	-
	(e) intellectual property	(7)	(23)
	(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**	**(201)**	**(946)**

Consolidated statement of cash flows		Current quarter $A'000s	Year to date (12 months) $A'000s
3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	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)
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)	(54)	(225)
3.10	**Net cash from / (used in) financing activities**	**(54)**	**3,243**

4.	**Net increase / (decrease) in cash & cash equivalents for the period**		
4.1	Cash & cash equivalents at beginning of period	20,066	24,818
4.2	Net cash from / (used in) operating activities (item 1.9 above)	790	(6,514)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(201)	(946)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(54)	3,243
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash & cash equivalents at end of period**	**20,601**	**20,601**

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	3,601	3,066
5.2	Term deposits	17,000	17,000
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)**	**20,601**	**20,066**

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	259
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)	790
8.2	Cash and cash equivalents at quarter end (item 4.6)	20,601
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	20,601
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**N/A**

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: 16 July 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.