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Quarterly Report – September 2023

Perth, Australia – 17 October 2023: Orthocell Limited (ASX: OCC, "Orthocell" or "the Company") is pleased to release its Quarterly Report for the quarter ended 30 September 2023.

Key highlights for the quarter:

1. **Orthocell reports increasing total revenue to $1.77 million in Q1 FY24, up 71% from Q1 FY23 of $1.03 million**
   - Increasing total revenue primarily driven by 14% growth in product revenue to $1.43 million in Q1 FY24 from $1.25 million in Q4 FY23, up 46% from the previous year (Q1 FY22) of $979k.
   - Quarterly product revenue has grown, on average, by 12% compounded for the last three quarters, following Striate+™ US and Remplir™ AUS product launches in Q2 FY23.

2. **Second US distributor now actively marketing and selling Striate+ as a private labelled product**
   - Subsidiary of Henry Schein, ACE Southern, launched the perFORM dental membrane (private label brand of Striate+) on 18 September 2023 at the American Association of Oral and Maxillofacial Surgeons (AAOMS) meeting in San Diego, California.
   - ACE Southern has an established network of US based dental service organisations (DSO's), providing consumables to multiple dental practices.
   - Additional distributor increases the representation of the product and the servicing of a wide range of dental customers in the US.

3. **Nerve repair study to support US regulatory approval commenced and on track for completion 1Q CY2024**
   - Study provides information regarding mechanism of action that it is not possible to collect in human clinical trials and will support product marketing initiatives, as well as international regulatory approval and reimbursement strategies.

4. **Pivotal tendon repair study on track for data read out in 4Q CY2023**
   - Randomised clinical trial comparing Orthocell's cell therapy for tendon repair to surgery for the treatment of lateral epicondylitis, is on track to be released 4Q CY2023. Pivotal study with data designed for an application to the Therapeutics Goods Administration (TGA) for inclusion on the Australian Register of Therapeutic Goods (ARTG).

5. **Strong balance sheet with $22.3m cash at bank at the end of the quarter**
   - Well positioned to continue to gain commercial traction with Striate+ now approved in US, EU/UK and AUS; Remplir approved in AUS and Company well-funded to gain US regulatory approval Remplir.

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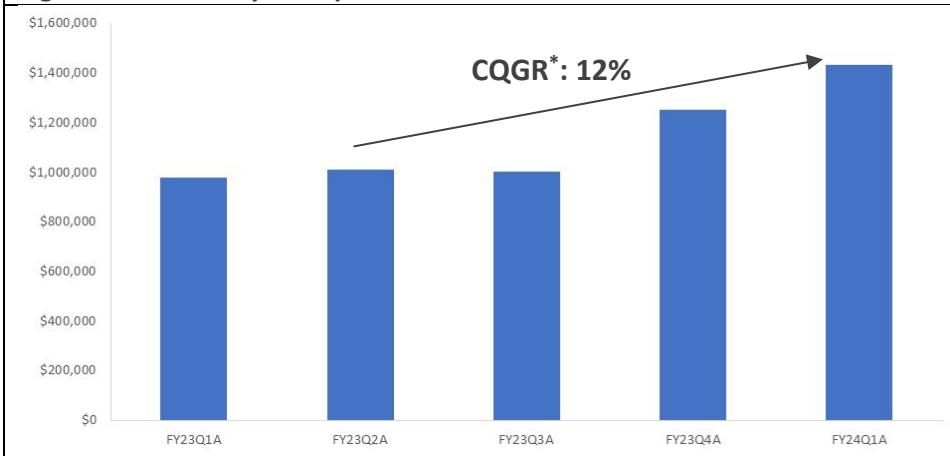
Orthocell Managing Director, Paul Anderson, said: "We are very pleased with the performance of our distribution partners and the continued quarterly increase in product revenue. Successful product launches of Remplir in Australia and Striate+ in the USA and Europe by our partners, has seen increases in surgeon engagement and broad uptake of our products, ensuring we are well positioned to continue to gain commercial traction and revenue growth."

Corporate and financial commentary

Total revenue for Q1 FY24 increased to $1.77 million (including product sales of $857k, interest received of $273k, Striate+ license revenue of $576k and sundry revenue of $0.59k), compared to $1.68 million for the prior quarter, up 71% on Q1 FY23 of $1.03 million. This was primarily driven by a 14% growth in product revenue (product sales and Striate+ license revenue) to $1.43 million in Q1 FY24 from $1.25 million in Q4 FY23, up 46% on Q1 FY23 of $979K, Figure 1.

Figure 1 – Quarterly total product revenue



Quarterly product revenue has grown, on average, by 12% (compounded for the last three quarters) following the US Striate+ and AUS Remplir product launches in Q2 FY23.

*CQGR = Compound Quarterly Growth Rate

Cash receipts received from customers, inclusive of GST, for Q1 FY24 increased to $898k, compared to $645k in the prior quarter. In line with the Company's expectations, net cash used in operating activities for the quarter was $2.3m. Most of the expenditure was allocated to commercial and R&D related activities. At the end of the quarter, Orthocell held a cash balance of A$22.3m. Orthocell's cash balance, market leading products and experienced management team, places the Company in a strong position to grow product sales alongside its distribution partners, BioHorizons and Device Technologies, and to execute its US market access program and commercialisation strategies for its breakthrough nerve repair medical device.

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

Strengthening the Board

Orthocell has been preparing for its next phase of commercial growth by strengthening the Board with the recent addition of John Van Der Wielen who contributes more than 35 years of global experience in wealth management, private banking, investments, and health insurance. He is a highly regarded healthcare executive, who is ideally suited to advance the commercialisation of Orthocell's unique medical devices and cellular therapies. The Company is also in discussions with other highly experienced executives to potentially join the Board and help to drive growth and shareholder value. Some recent changes include the retirement of Professor Lars Lidgren from the Orthocell Board and a temporary leave of absence of Ms Leslie Wise for

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personal reasons. The Orthocell Board now has six Directors comprising four Non-Executive Directors and two Executive Directors.

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+™ 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 Sales

BioHorizons completed a US product launch of Striate+ in November 2022, with a focus on supplying existing Key Opinion Leader (KOL) accounts and high-profile dental surgeons. The ramp up of product sold during the first 12-month period (01 September 2022 – 30 September 2023) has been significantly better than expected and continues to build momentum. Product uptake has been driven by the surgeons' preference for a high-quality dental membrane that is easier to use and facilitates better patient outcomes. **This has translated to 17% average quarterly growth rate (compounded for the previous three quarters) since US product launch in Q2 FY23 and a 50% increase in Striate+ sales in Q1 FY24 since the previous quarter Q4 FY23.**

Private label launched in the US

During the quarter, the Company successfully launched a private label called "PerFORM collagen membrane" (Striate+ product branded as Perform) with a subsidiary of Henry Schein. The Henry Schein subsidiary commenced in market promotion at the American Association of Oral and Maxillofacial Surgeons (AAOMS) meeting in San Diego, Calif (September 18, 2023). The subsidiary has an established network of US based dental service organisations (DSO's), which provide consumables to multiple dental practices and is actively marketing and distributing Perform on the same terms and conditions in the BioHorizons global licence and distribution agreement. Adding the subsidiary 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.

EU/UK and AUS market launch

BioHorizons have kicked off their EU and UK launch plans with attendance at the recent Oral Reconstruction Global Symposia in Rome, IT (May 18-20). BioHorizons is actively promoting Striate+ as the new leading dental membrane delivering high quality dental outcomes for the surgeon and the patient. During the quarter, Orthocell delivered a substantial order of Striate+ to BioHorizons to meet its initial KOL and other key account demands.

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BioHorizons is continuing to target key accounts in Australia and the Company is assisting the sales and marketing team with education and promotional activities.

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 sales

DVT officially launched Remplir in Australia in November 2022, with a focus on supplying existing othopaedic and plastic reconstructive KOL accounts. The ramp up of product sold since appointing DVT (01 September 2022 – 30 September 2023) has been significantly better than expected **with approximately 80 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 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. This has translated to **105% average quarterly growth rate (compounded for the previous three quarters) since AUS product launch in Q2 FY23 and a 39% increase in Remplir sales in Q1 FY24 since the previous quarter Q4 FY23.**

Orthocell has also assisted DVT with a series of targeted Remplir education and training events, including surgeon engagement roadshows, congress attendance and other scientific meetings in NSW, VIC, SA, NT and WA during the quarter. The DVT team has a very comprehensive customer engagement program with over 12 events scheduled for Q4 CY2023. Orthocell is assisting with the roll out of this program designed to continue the momentum in product adoption and grow the establishment of new orthopaedic and plastic reconstructive accounts.

The Company also recently attended the 78th American Society for Surgery of the Hand annual meeting in Toronto. This strategic meeting provided an opportunity to continue the US KOL engagement program, a critical part of the US market access strategy.

Nerve repair study for US regulatory approval

On 18 April 2023, Orthocell announced the commencement of a comparator study as part of a comprehensive pre-clinical and clinical development program in nerve repair and regeneration. The study provides information regarding mechanism of action that is not possible to collect in human clinical trials. The outcomes from the study will support product marketing initiatives and international regulatory approval and reimbursement strategies for Remplir.

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This preclinical study will be conducted by Professor Bill Walsh, Director of Surgical and Orthopaedic Research Laboratories (SORL) at the Prince of Wales Hospital in Sydney and the University of New South Wales. The Company anticipates study completion in Q1 2024 with results to follow. For more information click here.

The Company also continues to work closely with US regulatory advisers, to evaluate opportunities for expedited approval of Remplir for nerve regeneration.

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.

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$7.7bn[1] and growing.

The Company is currently conducting a clinical trial focussed on treatment of tennis elbow. The study is fully recruited, and the last patient received treatment in May 2022. **Outcomes from the study are anticipated to be released 4Q CY2023** and will provide pivotal data for an application to the Therapeutics Goods Administration (TGA) for inclusion on the Australian Register of Therapeutic Goods (ARTG).

The Company has been progressing its US commercialisation plans including investigations into technology scale up, FDA engagement and commercial preparation activities being to support a Phase 2b randomised controlled study for FDA submission.

Release authorised by:
Paul Anderson
Managing Director, Orthocell Ltd

[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.

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For more information, please contact:

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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™, 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.

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

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Name of entity

Orthocell limited

ABN	**Quarter ended ("current quarter")**
57 118 897 135	30 September 2023

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	898	898
1.2	Payments for:		
	(a) research & development (including allocated staff costs)	(2,508)	(2,508)
	(b) product manufacturing and operating costs	(360)	(360)
	(c) marketing, business development & investor relations	(150)	(150)
	(d) leased assets	(1)	(1)
	(e) staff costs (other than R&D staff)	(223)	(223)
	(f) administration & corporate costs	(344)	(344)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	387	387
1.5	Interest & other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants & tax incentives received	-	-
1.8	Other (contract revenue net of fees)	-	-
1.9	**Net cash from / (used in) operating activities**	**(2,301)**	**(2,301)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant & equipment	(156)	(156)
	(d) investments	-	-
	(e) intellectual property	(1)	(1)
	(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**	**(157)**	**(157)**

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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)	(50)	(50)
3.10	**Net cash from / (used in) financing activities**	**(50)**	**(50)**

4.	**Net increase / (decrease) in cash & cash equivalents for the period**		
4.1	Cash & cash equivalents at beginning of period	24,818	24,818
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,301)	(2,301)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(157)	(157)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(50)	(50)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash & cash equivalents at end of period**	**22,310**	**22,310**

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	3,310	6,818
5.2	Term deposits	19,000	18,000
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)**	**22,310**	**24,818**

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	636,456
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)	(2,301)
8.2	Cash and cash equivalents at quarter end (item 4.6)	22,310
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	22,310
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**10**

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-Oct-23

Authorised by: Peter Webse - Company Secretary
(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.

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