ortho·cell
advancing tissue repair & regeneration

Quarterly Report – March 2023

Perth, Australia – 27 April 2023: Orthocell Limited (ASX: OCC, "Orthocell" or "the Company") is pleased to release its Quarterly Report for the quarter ended 31 March 2023.

Key highlights for the quarter:

- Appointment of experienced US healthcare executive, Ravi I. Thadhani, MD, MPH, as independent Non-Executive Director to advance the commercialisation of Orthocell's unique medical devices and cellular therapies
- Appointment of internationally recognised orthopaedic surgeons, Professor Christopher Dy and Professor David Brogan, specialising in nerve transfer and peripheral nerve repair to its Medical Scientific Advisory Board
- Commencement of a comparator nerve repair study to support product marketing initiatives and international regulatory and reimbursement strategies
- Striate+™ global exclusive marketing and distribution partner, BioHorizons Implant Systems Inc. (BioHorizons), progresses Key Opinion Leader (KOL) product sales in the US and plans for market entry in the EU/UK and AUS
- Remplir™ exclusive distributor in Australia, Device Technologies, progresses KOL product sales and marketing plans to grow awareness and product adoption in Australia
- Orthocell is well-positioned to gain commercial traction with Striate+™ and Remplir™ in the US and Australia, and to expand into other global healthcare markets.

Orthocell Managing Director, Paul Anderson, said: "We are delighted with the appointments of Dr Ravi Thadhani to the Board, as well as Professor Christopher Dy and Professor David Brogan to the MSAB. These appointments add significant depth to our US specialist team and our ability to execute our commercialization plans."

"Our team continues to work alongside our partners assisting with education, marketing and establishment of key accounts. We are focussed on building long term mutually beneficial relationships with our distribution partners, and I look forward to what is shaping up to be a great year ahead for the Company."

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 soft tissue reconstruction and offers significant commercial potential in existing addressable markets of bone, tendon, nerve and cartilage, as well as wider applications in general surgical and soft tissue reconstructive applications. The global addressable market for CelGro™ is in excess of US$9.9bn[1] and growing. Orthocell is well positioned to establish CelGro™ as the best-in-class membrane for bone and soft tissue repair and to realise multiple commercial partnering opportunities.

[1] Company estimate for US, Japanese, European and Australian markets

Striate+™ for dental bone and tissue repair

Striate+™ is a market leading resorbable collagen membrane used in guided bone and tissue regeneration procedures. Striate+™ is manufactured by Orthocell at its quality-controlled facility in WA, using the Company's proprietary SMRT™ manufacturing technology. A facility upgrade to increase Striate+™ manufacturing capacity to >100,000 units per year was completed in December 2022. Clinical studies have shown Striate+™ supported transition from two- stage to single-stage dental procedures, 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. Its uptake is expected to be driven by surgeons' preference for high quality, easy to use devices facilitating better patient outcomes.

BioHorizons Implant Systems Inc. (BioHorizons)

In July 2022, the Company executed a global exclusive licence and distribution agreement with BioHorizons, one of the largest dental implant companies, for its Striate+™ premium dental membrane. In consideration of the license granted, Orthocell received in cash AU $21,461,686 million[2] net of fees.

BioHorizons is part of Henry Schein, Inc. (NASDAQ: HSIC) and a leading global provider of dental implants and tissue regeneration products for dentists and dental specialists. The company has a broad product offering, including dental implants, guided surgery, digital restorations and tissue regeneration solutions for the replacement of missing teeth. BioHorizons products are available in 90 markets around the world. For more information, visit biohorizons.com.

US market entry update

BioHorizons submitted first orders to the Company in September 2022 and completed a US product launch in November 2022. During the quarter BioHorizons continued its KOL-led market entry strategy, growing product awareness and adoption with high profile dental surgeons. To meet KOL demand, additional orders for Striate+™ were received by the Company and shipped to BioHorizon's distribution centers. Further orders for Striate+™ are expected in Q2 CY2023.

The Company continues to assist BioHorizons' sales and marketing team with US promotional activities including attendance at the recent Academy of Osseointegration annual meeting held in Phoenix, AZ (March 16-18, 2023). The annual meeting was attended by almost 2,000 dental surgeons and included Striate+™ hands on workshops, scientific presentations and commercial exhibits.

During the quarter, the Company continued discussions with BioHorizons regarding potential ways to leverage the Henry Schein group of global dental companies to increase distribution channels and accelerate product adoption in key markets.

EU/UK and AUS market entry

The Company is on track to transition from the Europe Medical Devices Directive (MDD) to the Medical Devices Regulation (MDR) CE Marking. Orthocell has received written confirmation from BSI Group, the Company's notified body, that all reviews and audits for compliance to MDR have been completed and no issues were identified that would prevent the issue of the MDR certificates.

[2] After transaction costs and assuming 1 United State Dollar is equal to 1.45 Australian Dollars

During the quarter, the Company and BioHorizons progressed plans to enter the EU and UK markets. In preparation for UK market entry, BioHorizons submitted their first purchase order and is planning to commence promotion and sales in Q2 CY 2023.

BioHorizons is also progressing well with the launch of Striate+ in the Australian market. The Company is assisting BioHorizons' sales and marketing team with planned education and promotional activities targeting the establishment of KOL accounts in major Australian cities.

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 manufactured using the Company's SMRT™ manufacturing technology to preserve the collagen structure for optimal tissue integration. 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 have been working with DVT to establish key accounts with leading plastic, reconstructive and orthopaedic specialists in Australia and New Zealand. First orders of Remplir™ were shipped to DVT in September 2022. Additional orders were received and shipped to DVT in the December and March quarters.

Orthocell has assisted DVT with a series of education and promotional events for Remplir, including attendance at the recent 2023 AOA Victorian Branch Annual Scientific meeting (17 – 19 February) and the 2023 Australian Hand Surgery Society in Sydney (01 - 04 March). Orthocell has also completed a series of targeted surgeon engagement roadshows in Brisbane and Sydney. Further events are planned in Adelaide and Perth in the June quarter.

Orthocell is also preparing for its inaugural Nerve Symposium to be held in Perth on 30 June 2023. The Symposium has been developed for plastic reconstructive and orthopaedic surgeons who treat nerve injuries and will be attended by international and local faculty. The purpose of the course is to provide surgeons with a broad understanding of peripheral nerve repair and regeneration and to advance surgical skills of nerve transfer using a collagen-based nerve device. The course will include a series of presentations from internationally recognised nerve repair experts. The cadaver workshop will focus on clinical experience in nerve transfer procedures and provide tools on how to define clinical indications for nerve transfer allowing for more reliable clinical outcomes.

Appointment of specialist US-based nerve surgeons to medical advisory board

On 29 March, Orthocell announced the appointment of internationally recognised orthopaedic surgeons, Professor Christopher Dy and Professor David Brogan, specialising in nerve transfer and peripheral nerve repair to its Medical Scientific Advisory Board. Professors Dy and Brogan are based at Washington University and Barnes-Jewish Orthopedic Center, one of the US's leading academic research institutions and hospitals,

and have been appointed to assist with clinical development and US market access for Orthocell's nerve repair medical device. Both surgeons bring a wealth of clinical and research expertise, including significant experience advancing pre-clinical and clinical research programs. With these additions to the specialist advisory team, Orthocell is ideally positioned to drive its market leading nerve repair medical device into the US market.

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

Commencement of nerve repair study
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.

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. For more information click here.

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[3] 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 will be released following the last patient 12 month follow up 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.

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

Corporate

Appointment of Independent Non-Executive Director Dr Ravi I. Thadhani

On 8 March 2023 Orthocell appointed experienced US healthcare executive, Ravi I. Thadhani, MD, MPH, as independent Non-Executive Director. Dr Thadhani has more than 30 years of specialist experience working in US healthcare sector; is a highly regarded executive, medical administrator and researcher; and is ideally suited to support the next phase of Orthocell's development. Dr Thadhani brings a wealth of experience as an advisor to the US FDA and consultant to multiple global healthcare companies, including extensive experience advancing novel research programs, advising on US regulatory pathways and commercialisation of devices and therapeutics.

Cashflow update

Orthocell's net cash used in operating activities for the quarter was ($2.45m). 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$24.20m. Orthocell's strong cash position enables the Company to drive further development of its Remplir™ nerve product and pipeline of regenerative medicine products, delivering significant shareholder value.

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

Release authorised by:

Paul Anderson
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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

Name of entity

Orthocell limited

ABN	**Quarter ended ("current quarter")**
57 118 897 135	31 March 2023

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	265	1,227
1.2	Payments for:		
	(a) research & development (including allocated staff costs)	(1,680)	(5,179)
	(b) product manufacturing and operating costs	(520)	(1,438)
	(c) marketing, business development & investor relations	(130)	(490)
	(d) leased assets	(1)	(2)
	(e) staff costs (other than R&D staff)	(387)	(938)
	(f) administration & corporate costs	(289)	(1,067)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	291	414
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)	-	21,462
1.9	**Net cash from / (used in) operating activities**	**(2,451)**	**13,989**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant & equipment	(83)	(609)
	(d) investments	-	-
	(e) intellectual property	(42)	(84)
	(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**	**(125)**	**(693)**

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)	-	-
3.2	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)	(37)	(112)
3.10	**Net cash from / (used in) financing activities**	**(37)**	**(112)**

4.	**Net increase / (decrease) in cash & cash equivalents for the period**		
4.1	Cash & cash equivalents at beginning of period	26,819	11,022
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,451)	13,989
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(125)	(693)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(37)	(112)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash & cash equivalents at end of period**	**24,206**	**24,206**

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	2,206	2,819
5.2	Term deposits	22,000	24,000
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)**	**24,206**	**26,819**

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	283
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)	(2,451)
8.2	Cash and cash equivalents at quarter end (item 4.6)	24,206
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	24,206
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**9.88**

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: 27 April 2023

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.