Quarterly Report – June 2022

Perth, Australia – 29 July 2022: Orthocell Limited (ASX: OCC, "Orthocell" or "the Company") is pleased to release its Quarterly Report for the quarter ended 30 June 2022.

Key highlights for the quarter:

- **Orthocell completes Striate+™ global exclusive licence and manufacturing agreements with BioHorizons Implant Systems Inc. (BioHorizons)**
- **In consideration of the license granted, Orthocell has received in cash AU $21,461,686 million[1] (USD $14,774,225 million), net of fees**
- **Facility upgrade to enable scale up of Striate+™ manufacturing capacity to >100,000 units per year on track for construction completion 31 July, 2022**
- **Final data read out of all patients in Orthocell's nerve reconstruction trial showed 85% (23 of 27) of nerve repairs with Rempir™ at 24 months post treatment resulted in functional recovery of target muscles closest to the repair site**
- **Submitted application for inclusion of Remplir™ on the Prostheses List to enable reimbursement by insurers in Australia**
- **The final data read out from the OrthoATI™ Phase 2a study planned for Q3 CY2022**
- **A$2.1m R&D tax incentive refund received**

Orthocell Managing Director, Paul Anderson, said: "BioHorizons is a leading global provider of dental implant and tissue regenerative products with specialist capabilities and resources to expand the marketing, promotion and supply of Striate+™ worldwide. We are delighted to be working with BioHorizons which has established relationships with dentists and dental specialists and a successful track record in driving the market entry of high-quality products. The Agreements with BioHorizons represent a significant milestone for Orthocell and provide further external commercial and technical validation of the CelGro™ collagen scaffold platform, from which the Striate+™ dental products were developed."

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, and wider applications in general surgical and soft tissue reconstructive applications. The global addressable market for CelGro™ is in excess of US$9.9bn[2] 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.

Striate+™ for dental bone and tissue repair

Orthocell entered into an exclusive patent and trademark licence agreement (Licence Agreement) and an exclusive distribution and supply agreement (Distribution Agreement) with Delaware corporation BioHorizons Implant Systems Inc. (BioHorizons) during the quarter. In consideration of the license

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

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

granted, Orthocell has received in cash AU $21,461,686 million[1] (USD $14,774,225 million), net of fees. Under this agreement Orthocell will grant BioHorizons an exclusive licence of two patent families, covering a collagen scaffold for cell growth and a method for producing a collagen membrane, together with associated patent applications, improvements and know-how and the Striate+ trademark (together, the Agreements).

Orthocell Managing Director Paul Anderson, said: *"We are delighted to have received funds from BioHorizons, strengthening our cash position, enabling us to drive the further development of our Remplir™ nerve product and pipeline of regenerative medicine products."*

Striate+™ is a market leading resorbable collagen membrane used in guided bone and tissue regeneration procedures. Its uptake is expected to be driven by surgeons' preference for high quality, easy to use devices facilitating better patient outcomes. Clinical studies have shown Striate+™ supported transition from two-stage to single-stage dental procedures, reducing the procedure time by several months. This is of significant interest to patients and clinicians due to potential improvements in efficiency and efficacy of dental procedures.

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.

Orthocell will manufacture and supply BioHorizons with quantities of Striate+™ products that embody the licensed IP and grant BioHorizons exclusive distribution rights in respect of those products in the Field. Striate+™ is manufactured by Orthocell at its quality-controlled Good Manufacturing Practices (GMP) licensed facility in WA, using the Company's proprietary SMRT™ manufacturing technology. Facility upgrade to enable scale up Striate+™ manufacturing capacity to >100,000 units per year on track for construction completion 31 July, 2022.

Remplir™
nerve wrap

Remplir™ for nerve regeneration

The final data read out of all patients in the Remplir™ (previously CelGro®) nerve regeneration trial at 24 months post-treatment was released in June, 2022. Patients received one or more nerve repairs augmented with Remplir™ in one or both upper limbs. Recovery after treatment was assessed by grading the strength of target muscles[3] closest to the site of nerve repair. Follow-up data at 24 months post treatment was available for 14 of 19 patients involving 27 nerve repairs. Results showed that 85% (23 of 27) of nerve repairs resulted in functional recovery of target muscles closest to the repair site.

Positive clinical data demonstrates nerve repair with Remplir™ following injury to the spinal cord, brachial plexus and other peripheral arm/hand nerves, consistently restores arm and hand function. Functional gains were not only maintained but continued to improve between 12- and 24-months post-treatment.

[3] *British Medical Research Council Grading System (MRC grade), with a score of 0 to 5. A score of zero (0) indicates no nerve connection to the muscle (ie., no recovery), a score of five (5) is given to muscles with normal power/strength. A score of 3 or better is clinically defined as a meaningful functional recovery.*

The Company believes Remplir™ to be an important step forward for improving 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 patients with these complex injuries. Remplir™'s global addressable market in peripheral nerve repair is estimated to be worth more than US$7.5 billion per annum, with approximately 3 million procedures that could use Remplir™ completed each year.

Next Steps

Remplir™ received Australian regulatory approval in March 2022 and has focused on achieving reimbursement by insurers submitting its application for inclusion on the Prostheses List. The Company has also progressed discussions with potential marketing and distribution partners in Australia.

The Australian market entry strategy involves expanding the Key Opinion Leader network using Remplir™ in peripheral nerve repair procedures and engaging a high-quality distributor. This strategy will assist in establishing Remplir™ as the leading nerve repair device. A product awareness program was launched at the 2022 Australian Hand Surgery Society Annual Scientific Meeting, where pre-clinical and clinical data was presented. This was followed with another presentation at the 2022 Shoulder and Elbow Society Australia Biennial Conference in Sydney from 31 March to 03 April 2022 and an exhibition at 2022 Plastic Surgery Congress in Queensland from 16-18 June, 2022.

The Company continues to work closely with Veranex (previously Experien Group), as the Company's US regulatory advisers, to evaluate opportunities for expedited approval of Remplir™ for nerve regeneration. During the quarter, the team progressed a US FDA submission to confirm the most appropriate US regulatory pathway, potential for inclusion in expedited programs and what this will mean for reimbursement value for the product.

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. Only cells of the highest purity and potency are returned to the patient, ensuring high quality tissue repair.

OrthoATI™
for regeneration of human tendon

OrthoATI™

OrthoATI™ is a world-leading cell therapy developed to treat 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[2] and growing.

The Company is currently conducting two clinical trials with OrthoATI™ - the first is focused on the rotator cuff and the second on tennis elbow tendon defects. The Company announced the first statistically significant results from its Phase 2a randomised, multi-centre, controlled rotator cuff tendon clinical study ('RC Study') in December 2021. In light of the initial study results, 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.

The release of the final data from the Phase 2a study is now expected for release this quarter. These data include results from the treatment of the patients in the study that received steroids and after poor results –

elected to "cross-over" to be treated with OrthoATI™. Success in this patient population will further confirm the efficacy of OrthoATI™ firmly placing Orthocell in a strong position to progress its US commercialisation strategy to deliver the first injectable cell therapy in orthopaedics for the treatment of chronic tendon injuries.

This quarter, Professor Minghao Zheng (Chief Scientific Officer, Orthocell Ltd) presented at The Orthobiologics Institute 2022 meeting in Hollywood FL from the 9-11 June highlighting OrthoATI™ is a safe and effective treatment for patients suffering from rotator cuff tendinopathy with intrasubstance tendon tear compared directly to the standard of care (steroid injections).

The second OrthoATI™ clinical trial focussed on treatment of tennis elbow is fully recruited and the last patient received treatment in May, 2022. Data will be released following the last patient 12 month follow up.

Corporate
Orthocell's net operating cash inflows for the quarter were A$182k. 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$11.022m and subsequently received AU $21,461,686 million[1] (USD $14,774,225 million), net of fees in consideration for the Licence Agreement granted to BioHorizons.

Orthocell's strong cash position enables the Company to drive the further development of our 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:

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ortho·cell
advancing tissue repair & regeneration

About Orthocell Limited

Orthocell is focused on regenerating mobility for patients by developing innovative 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 repair and healing in a variety of orthopaedic, reconstructive, and surgical applications. CelGro™ has received regulatory approval in the EU, Australia and the US for bone and soft tissue regeneration in dental procedures. The Company is investigating other clinical uses for CelGro in peripheral nerve and tendon repair. The Company's other major products are personalised cell therapies Autologous Tenocyte Implantation (OrthoATI™) and Autologous Chondrocyte Implantation (OrthoACI™), which aim to regenerate damaged tendon and cartilage tissue. Orthocell is moving forward with clinical studies for OrthoATI™ designed to assist in the US (FDA) approval process.

For more information on Orthocell, please visit www.orthocell.com.au 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 2022

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	407	1,453
1.2	Payments for:		
	(a) research & development (including allocated staff costs)	(1,578)	(7,039)
	(b) product manufacturing and operating costs	-	-
	(c) marketing, business development & investor relations	(366)	(898)
	(d) leased assets	(1)	(3)
	(e) staff costs (other than R&D staff)	(222)	(718)
	(f) administration & corporate costs	(209)	(1,340)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	7	84
1.5	Interest & other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants & tax incentives received	2,144	2,144
1.8	Other	-	-
1.9	**Net cash from / (used in) operating activities**	**182**	**(6,317)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant & equipment	(389)	(608)
	(d) investments	-	-
	(e) intellectual property	(17)	(18)
	(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**	**(406)**	**(626)**

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)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of share options	-	1,636
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 (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**-**	**1,636**

4.	**Net increase / (decrease) in cash & cash equivalents for the period**		
4.1	Cash & cash equivalents at beginning of period	11,246	16,329
4.2	Net cash from / (used in) operating activities (item 1.9 above)	182	(6,317)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(406)	(626)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	1,636
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash & cash equivalents at end of period**	**11,022**	**11,022**

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	4,022	1,846
5.2	Term deposits	7,000	9,400
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)**	**11,022**	**11,246**

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	233
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)	182
8.2	Cash and cash equivalents at quarter end (item 4.6)	11,022
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	11,022
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: 29 July 2022

Authorised by: Simon Robertson, 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.