ortho·cell
advancing tissue repair & regeneration

Quarterly Report – September 2022

Perth, Australia – 31 October 2022: Orthocell Limited (ASX: OCC, "Orthocell" or "the Company") is pleased to release its Quarterly Report for the quarter ended 30 September 2022.

Key highlights for the quarter:

- **Following completion of the Striate+™ global exclusive licence and manufacturing agreements with BioHorizons Implant Systems Inc. (BioHorizons), Orthocell received AU $21,461,686 million[1] (USD $14,774,225 million), net of fees**
- **Completion of facility upgrade to enable scale up of Striate+ manufacturing capacity to >100,000 units per year with final validations expected in Q4 CY2022**
- **Device Technologies appointed as exclusive distributor in Australia of Orthocell's nerve repair device Remplir™**
- **First purchase orders received from newly appointed distribution partners for Orthocell's flagship collagen medical device products Striate+ and Remplir**
- **Positive results from OrthoATI™ rotator cuff tendon clinical study crossover patient extension arm**
- **Orthocell is now well-positioned to gain commercial traction with Striate+ and Remplir in the US and Australia and expand into other global healthcare markets**

Orthocell Managing Director, Paul Anderson, said: "We are delighted to be working with BioHorizons and Device Technologies as our strategic marketing and distribution partners. Establishing these partnerships represents a significant milestone for Orthocell, and provides further external commercial validation of the CelGro™ collagen scaffold platform, from which the Striate+ and Remplir products were developed. Market entry preparations are progressing well and we look forward to growing product awareness and key accounts alongside our partners."

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[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+™
more than a barrier membrane

Striate+™ for dental bone and tissue repair

Striate+ is a market leading resorbable collagen membrane used in guided bone and tissue regeneration procedures. 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

[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

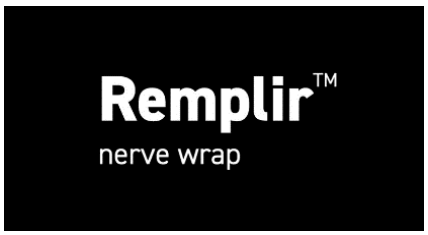
procedure time by several months. This is of significant interest to patients and clinicians due to potential improvements in efficiency and efficacy of dental procedures.

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 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).

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 facility in WA, using the Company's proprietary SMRT™ manufacturing technology. A facility upgrade to scale up Striate+ manufacturing capacity to >100,000 units per year is on track, with construction completed in July, 2022, and final validations expected to be completed in Q4 CY2022.

First orders for Striate+ were shipped to BioHorizons distribution center in September and the Company continues to assist the sales and marketing team at BioHorizons prepare for US market entry by hosting targeted online Striate+ training programs, highlighting the products ease of use and high-quality patient outcomes. BioHorizons will be promoting Striate+ for use in dental guided bone and tissue regeneration procedures at the upcoming American Academy of Periodontology Annual Meeting in Phoenix, Arizona between the 27th – 30th October, with active US sales representation of the product to follow in November, 2022.



Remplir™ for nerve regeneration

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.

During the quarter the Company announced it has appointed Device Technologies ("DVT") as its exclusive distributor of Remplir for peripheral nerve repair across Australia and New Zealand. The distributor agreement follows the Australian market approval for its Remplir peripheral nerve repair device received in March 2022 and the Company's application for inclusion of Remplir™ on the Australian Prostheses List. Inclusion on the Prostheses List will enable practitioners to receive reimbursement from private insurers for use of Remplir in approved peripheral nerve repair procedures, reducing costs to the patient.

Device Technologies will market and distribute Remplir, undertaking targeted promotion activities, initiating sales, and expanding the network of referring plastic and orthopaedic surgeons. The exclusive distribution agreement has an initial term of five years and enables Orthocell access to this strategic market, with a growing uptake of Australian Made, high-quality healthcare products.

First orders of Remplir were shipped to DVT in September. Orthocell have been actively working with the internal sales and marketing team at DVT preparing for Australian market entry, leading in-person product training sessions and participating in marketing workshops. DVT are focused on the establishment of key accounts with leading plastic, reconstructive and orthopaedic specialists. Representatives from DVT attended the South Australian Hand Society Meeting on the 24th of October, the 2022 Royal North Shore Shoulder Symposium on Friday 21st October, and will be attending the Australian Orthopaedic Association in Christchurch, New Zealand from the 30th October to the 3rd November, to exhibit and promote Remplir for use in peripheral nerve repair procedures.

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.

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.

Participants in the RC study were either treated with OrthoATI or corticosteroid injection. Following treatment, assessment of pain and shoulder function showed that patients in the OrthoATI group had significantly better results compared to the steroid group at all post-treatment time points. Patients who received steroid injection in the original study were still experiencing pain and loss of function in their affected shoulder at the end of the study. The majority (9 of 11 patients) subsequently requested treatment with OrthoATI. In the 12 months after their OrthoATI treatment, none of the patients required additional medical treatment for their shoulder injury. They also reported almost complete resolution of pain and experienced clinically important improvements in shoulder function. In short, their treatment with OrthoATI mirrored the outcomes experienced by the patients who received OrthoATI in the original trial. These positive outcomes are encouraging and provide additional support to those observed from the original trial.

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.

Next Steps
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.

Corporate

In July 2022 Orthocell 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 net operating cash inflows for the quarter were A$18.8m. 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$29.4m.

Orthocell's strong cash position enables the Company to drive the 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
Managing Director, Orthocell Ltd
For more information, please contact:

General & Investor enquiries

Paul Anderson
Orthocell Limited
Managing Director
P: +61 8 9360 2888
E: paulanderson@orthocell.com.au

Media enquiries

Haley Chartres
H^CK Director

P: +61 423 139 163
E: haley@hck.digital

About Orthocell Limited

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 and is cleared for use in US FDA (510k), Australia (ARTG) and Europe (CE Mark). Remplir™, for peripheral nerve reconstruction, recently received approval in Australia (ARTG). 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	30 September 2022

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	463	463
1.2	Payments for:		
	(a) research & development (including allocated staff costs)	(1,989)	(1,989)
	(b) product manufacturing and operating costs	(316)	(316)
	(c) marketing, business development & investor relations	(144)	(144)
	(d) leased assets	(1)	(1)
	(e) staff costs (other than R&D staff)	(234)	(234)
	(f) administration & corporate costs	(491)	(491)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	39	39
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	21,462
1.9	**Net cash from / (used in) operating activities**	**18,789**	**18,789**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant & equipment	(310)	(310)
	(d) investments	-	-
	(e) intellectual property	(65)	(65)
	(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**	**(375)**	**(375)**

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 (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**-**	**-**

4.	**Net increase / (decrease) in cash & cash equivalents for the period**		
4.1	Cash & cash equivalents at beginning of period	11,022	11,022
4.2	Net cash from / (used in) operating activities (item 1.9 above)	18,789	18,789
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(375)	(375)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash & cash equivalents at end of period**	**29,436**	**29,436**

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	3,436	4,022
5.2	Term deposits	26,000	7,000
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)**	**29,436**	**11,022**

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	528
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)	18,789
8.2	Cash and cash equivalents at quarter end (item 4.6)	29,436
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	29,436
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: 31/10/2022

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.