

Quarterly Report – March 2022

Perth, Australia – 29 April 2022: Orthocell Limited (ASX: OCC, “Orthocell” or “the Company”) is pleased to release its Quarterly Report for the quarter ended 31 March 2022.

Key highlights for the quarter:

- **Remplir™ nerve repair device receives Australian regulatory approval** for introduction into the Australian nerve repair and regeneration market
- **Application for inclusion of Remplir™ on the Prostheses List on track** for submission in Q2 CY2022
- **Final Remplir™ 24 month results of all patients in the nerve regeneration study on track** for Q2 CY2022
- **Significant Striate+™ US market entry progress** with sale of over 1,500 Striate+™ units achieved, and commencement of facility upgrade to enable scale up Striate+™ manufacturing capacity to >100,000 units per year
- **Striate+™ distributor discussions progressed** and the Company is in advanced discussions to engage its first US distributor and establish Striate+™ as the premium dental membrane
- **The final data from the OrthoATI™ Phase 2a study on track for Q2 CY2022**

Orthocell Managing Director, Paul Anderson, said: “We are delighted to have Remplir™ added to the Australian Register of Therapeutic Goods (ARTG) allowing it to be marketed and sold within Australia. Remplir™ is the only Australian manufactured medical device for nerve repair to gain Australian regulatory approval and is a significant inflection point for our Company. This is combined with significant progress in our US market entry for Striate+™ and we are well-positioned to secure a US distribution partner. We look forward to what is shaping up to be a very exciting year ahead for the Company.”

CelGro™ Platform

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\$9.9bn¹ 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.





Figure 1: CelGro™ Platform Technology



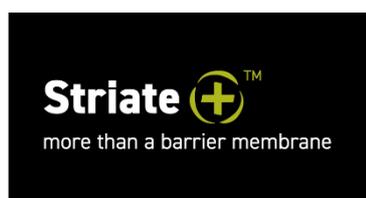
Remplir™ for nerve regeneration

In March 2022, the Company announced Australian market approval for its Remplir™ peripheral nerve repair device, for introduction into the Australian nerve repair and regeneration market.

Inclusion of Remplir™ on the Australian Register of Therapeutic Goods (ARTG) follows a successful Conformity Assessment by the TGA with respect to the evaluation of the safety and performance of Remplir™ in peripheral nerve repair. The Company is now focused on achieving reimbursement by insurers and has progressed its application for inclusion on the Prostheses List. Application for inclusion on the Prostheses List is on track for submission in Q2 CY2022. Since gaining market approval, the Company has achieved approval for public hospitals use including Fiona Stanley Fremantle Hospital Group and private hospitals use, for workers compensation cases.

The Australian market entry strategy involves expanding the Key Opinion Leader network using Remplir™ in peripheral nerve repair procedures and potentially 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.

The Company also continued 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.



Striate+™ for dental bone and tissue repair

Orthocell has successfully completed the regulatory phase for use of Striate+™ (previously branded as CelGro™ Dental) in dental bone and soft tissue repair procedures, successfully attaining AUS, US and EU approval. Key market approvals and key opinion leader product use are essential factors in securing a strategic partner to manage the distribution and marketing of

Striate+™. With scalable manufacturing and an increasing number of industry leading dental surgeons



advocating on our behalf, Orthocell is well positioned to execute on its partnering and commercialisation strategy.

United States Market

Since gaining US market approval, the Company has focussed on preparing for market entry establishing a logistics solution, developing a key opinion leader (KOL) network and implementing a KOL led education and product awareness program (clinician advocacy program).

During the quarter the Company:

- **Progressed the clinician advocacy program and achieved a US key opinion leader sales growth milestone**

The Company's clinician advocacy program has progressed significantly, with eighteen highly respected KOL's across the EU, UK, US and AUS, who are actively representing the Company as product ambassadors and using Striate+™ in their dental surgeries. Product sales of Striate+™ from the US KOL's alone has reached over 1,500 units. These industry-leading clinicians continue to assist the Company in growing product awareness, expanding the network of key accounts and supporting ongoing discussions with potential distribution partners.

- **Commenced the upgrade of its existing facility to enable scale up Striate+™ manufacturing capacity to >100,000 units per year**

The Company has commenced the construction project to enable the scale up of manufacturing capacity to >100,000 Striate+™ units per annum. The cleanroom, equipment and operator costs are fully funded, and commissioning of the manufacturing facility is expected in Q4 CY2022.

- **Advanced discussions with distributors** with the aim to engage a high-quality partner to manage marketing and distribution and establish Striate+™ as the premium dental membrane

Australian Market

Samson Medical Technologies (the Company's distributor in Australia) is actively promoting Striate+™ through education webinars, product workshops, congress attendance and social media programs. During the quarter, Samson Medical Technologies hosted a webinar on 23rd February titled, "an overview of grafting materials" targeting dental implantologists, attended the Australian Society of Implant Dentistry on 9 March and sponsored the ANZAOMS Vic/Tas branch meeting on 16 March. This successful marketing program has translated to growth in the establishment of key accounts and Company expects this to translate to product use in CY2022.

UK and EU Market

The Company has been preparing for the post-COVID anticipated return of demand for high quality products, such as Striate+™, to facilitate rapid and high-quality dental procedures by continuing to invest in its clinician advocacy program and targeted digital marketing program. This has resulted in the establishment of accounts in Spain and France. In particular, sales in France to dental implantologists has reached over 1,800 units.



SmrtGraft™
bioactive matrix

CelGro™ Pipeline

SmrtGraft™ (previously named CelGro™ tendon repair)

The Company attended the 2022 Shoulder and Elbow Society Australia Biennial Conference in Sydney from 31 March to 3 April 2022. The Company's CSO and inventor, Professor Minghao Zheng, presented the publication of a prospective study ("SmrtGraft Study") evaluating the structural and biological properties of SmrtGraft™ and assessing the safety and effectiveness of its use in the augmentation of rotator



cuff tendon surgical repairs. The findings represent a substantial advance in improving patient outcomes by reducing rates of revision surgeries.

The SmrtGraft™ Study was published in the Journal of Orthopaedic Translation, a highly regarded peer-reviewed scientific journal. The publication follows a successful collaboration between Professor Allan Wang (The University of Western Australia), Dr Will Haynes (Umhlanga Ridge Orthopaedic Centre, South Africa), Dr Bill Breidahl (Perth Radiological Clinic) and Chief Scientific Officer, Professor Minghao Zheng at the Perron Institute and The University of Western Australia. The publication may be viewed here: [SmrtGraft™ Publication](#).



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\$7.7bn¹ 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. During the previous quarter the Company announced the first statistically significant results from its Phase 2a randomised, multi-centre, controlled rotator cuff tendon clinical study ('RC Study'). This quarter, Professor Allan Wang, chief investigator of the RC Study attended the 2022 Shoulder and Elbow Society Australia Biennial Conference in Sydney (31 March to 03 April 2022) and presented the RC study results highlighting that 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 final data from the Phase 2a study will be available 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.

In light of the initial study results, the Company is accelerating its US commercialisation plans with technology scale up, FDA engagement and commercial preparation activities being advanced to support a Phase 2b randomised controlled study for FDA submission.

The tennis elbow study is fully recruited and last patient treatment is currently planned for completion in Q2 CY2022.

Corporate

Orthocell's net operating cash outflows for the quarter were A\$2,355k. 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\$11.2m.

Orthocell's strong cash position enables the Company to progress key regulatory approvals and its commercialisation strategy, 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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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](https://twitter.com/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 its 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

57 118 897 135

Quarter ended ("current quarter")

31 March 2021

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	313	1,046
1.2 Payments for:		
(a) research & development (including allocated staff costs)	(2,030)	(5,449)
(b) patent & trademark fees	(7)	(247)
(c) marketing, business development & investor relations	(138)	(508)
(d) leased assets	(1)	(2)
(e) staff costs (other than R&D staff)	(119)	(496)
(f) administration & corporate costs	(373)	(904)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	77
1.5 Interest & other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants & tax incentives received	-	-
1.8 Other	-	-
1.9 Net cash from / (used in) operating activities	(2,355)	(6,483)
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant & equipment	(44)	(219)
(d) investments	-	-
(e) intellectual property	(1)	(17)
(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	(45)	(236)

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	-	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	13,646	16,329
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(2,355)	(6,483)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(45)	(236)
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	11,246	11,246

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	1,846	4,246
5.2 Term deposits	9,400	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)	11,246	13,646

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	-
<i>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</i>	

7. Financing facilities available	Total facility amount at quarter end \$A'000s	Amount drawn at quarter end \$A'000s
<i>Note: the term 'facility' includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the position.</i>		
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 Total financing facilities	-	-

7.5 Unused financing facilities 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)	(2,355)
8.2 Cash and cash equivalents at quarter end (item 4.6)	11,246
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	11,246
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	5

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-Apr-22

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.