ortho·cell
advancing tissue repair & regeneration

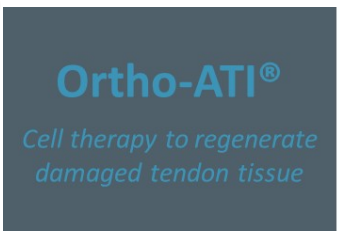
Quarterly Report – September 2021

Perth, Australia – 29 October 2021: Orthocell Limited (ASX: OCC, "Orthocell" or "the Company") is pleased to release its Quarterly Report for the quarter ended 30 September 2021.

Key highlights for the quarter:

- **The last patient treated in the randomised clinical study comparing Orthocell's tendon regeneration therapy (Ortho-ATI®) to corticosteroids has completed study - results expected in Q4, 2021 which is a significant milestone for the Company**
- **Significant progress made towards Striate+ US market entry** with incorporation of Orthocell's wholly owned Delaware LLC to enable product supply, set up of a high-quality US warehouse and logistics solution, key influencer/opinion leader engagement and high impact product launch plans completed with Sunrise Dental Solutions Group and planned for Seattle Study Club;
- **Samson Medical Technologies appointed as exclusive distributor in Australia of Orthocell's Striate+**, for bone and soft tissue repair;
- **Completion of pre-clinical Anterior Cruciate Ligament (ACL) reconstruction study** indicating that a novel CelGro® collagen 'rope' has potential to be the **first off-the-shelf biological device capable of improving ACL reconstruction outcomes**; and
- **CelGro® patents granted in Canada and Hong Kong for sutureless repair of soft tissue defects** covering the method of using CelGro® to repair a defect in soft tissue, such as tendons, ligaments and nerves, avoiding the use of damaging sutures.

Orthocell Managing Director, Paul Anderson said: "The Company has had a very busy quarter, gathering and analysing the Ortho-ATI rotator cuff tendon study data, progressing the US and AUS market entry of Striate+ and the US regulatory program for our CelGro® nerve regeneration device. I am excited by the potential of our Australian invented and manufactured products and look forward to what is shaping up to be a very exciting period for the Company."



Ortho-ATI®

Ortho-ATI® is a world-leading cell therapy developed to treat chronic degenerative tendon injuries (tendinopathy / tendonitis). Ortho-ATI® can be used in both surgical and non-surgical applications and is at the forefront of a large and increasing market opportunity, estimated to be worth >US$7.7bn[1] and growing.

The Company is currently conducting two clinical trials with Ortho-ATI® - the first is focused on the rotator cuff and the second on tennis elbow tendon defects. During the quarter the Company announced that the last patient in the Autologous Tenocyte Injection (Ortho-ATI®) rotator cuff tendon study ('RC Study') has completed their 12-month follow-up visit. The RC Study was designed

to assess the effectiveness of Ortho-ATI®, compared to corticosteroids, as a non-surgical treatment to a difficult clinical problem with limited treatment options. Should the Ortho-ATI® shoulder tendon study meet its objectives, it will be the first high-quality randomised controlled trial successfully completed for tendon repair globally, 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.

The Company remains on track to complete data analysis for the RC Study with data expected to be available in Q4, 2021. The Company will provide further updates in relation to the market opportunity for Ortho-ATI®, the regulatory strategy to be pursued to enable rapid approval by FDA and also the study design to facilitate the first global approval of a cell therapy for tendon injuries. Plans for the development of a US commercial and development team are well advanced and are pending successful outcomes from this important study.

The tennis elbow study is 92% recruited and plans to be fully recruited in CY 2021.

CelGro®
Soft tissue reconstruction platform medical device

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[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.

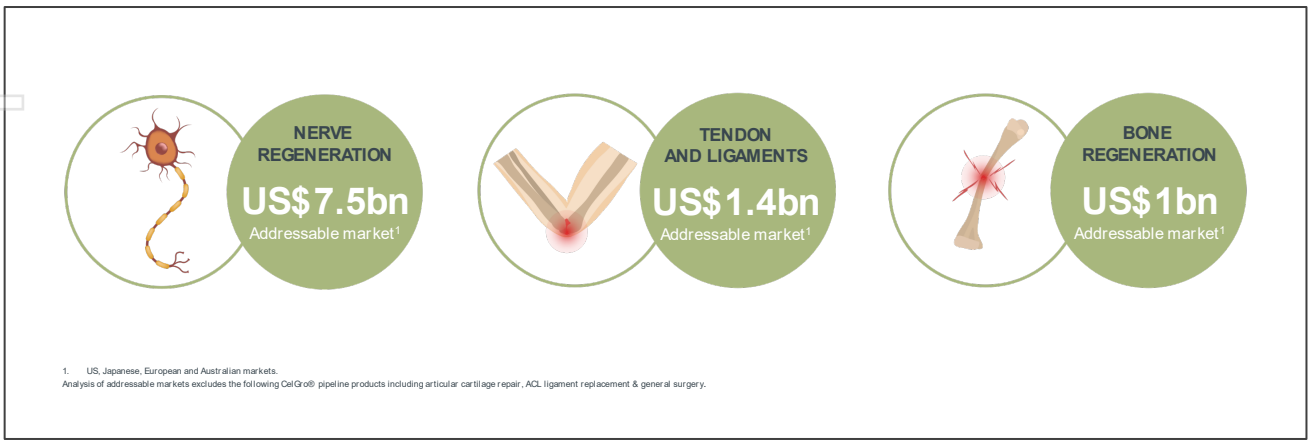


Figure 1: CelGro® Platform Technology

1. 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

Orthocell received FDA 510(k) clearance in January, 2021 to market and supply Striate+ for dental bone and tissue regeneration procedures in the US dental market, estimated at US$500 million per annum[1]. Since gaining US market approval the Company has focused on preparing for market entry incorporating a Delaware limited liability company to enable supply of product and the implementation of a warehouse and logistics solution. During the quarter the Company:

- **Completed the Sunrise Dental Solutions Group launch** showcasing Striate+ at the Sunrise Summit in October, 2021. One of Orthocell's key influencers, Dr Pamela Ray presented her experiences with Striate highlighting its advantages over current products. The expert session was captured on video and will be used in high impact digital marketing initiatives.
- **Finalised preparations for the November 2021 Seattle Study Club launch** – The Seattle Study Club is a network of over 5,700 dental clinicians (predominantly US based) interested in furthering their knowledge to provide the highest quality dental care to patients. The launch involves an announcement to all members sharing product feedback from six Striate+ product advocates with extensive social media followings providing members with tailored education material, an introduction to Striate+ and clear instructions on how to gain access to the product.
- **Continued development of key influencer/opinion leader videos** capturing user feedback and highlighting the distinct Striate+ advantages of better handling characteristics and higher quality dental outcomes; and
- **Progressed the establishment of US key influencer/key opinion leader accounts**. First US KOL orders expected shortly.

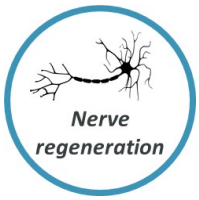
Australian Market

In July 2021, the Company engaged Samson Medical Technologies as exclusive distributor in Australia of Orthocell's Striate+, for bone and soft tissue repair. Samson Medical is a leading distributor of innovative medical devices with an experienced team to assist in managing the market entry, promotion and distribution of Striate+. The engagement of Samson Medical Technologies follows inclusion of Striate+ on the Australian Prostheses List enabling dental practitioners to receive reimbursement from private insurers. With COVID-19 restrictions lifting on the east coast of Australia Samson has been actively marketing the product and ensuring key accounts have sufficient stock to meet expected demand for dental procedures.

During the quarter the Company was also accepted to present Striate+ pre-clinical and clinical data at the ADA FDI 2021 World Dental Congress providing an opportunity to showcase high quality dental bine outcomes following the use of Striate+ periodontal membrane.

UK and EU Market

During the quarter, COVID-19 restrictions began to ease and some dental practices resumed patient treatments. The Company has been preparing for the 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. Recently, the Company attended in person conferences in the UK including the FMC Dental Conferences in London and Exeter. Orthocell has also facilitated educational workshops with highly regarded practitioners with the aim of establishing KOL accounts.



2. Remplir™ for nerve regeneration

In August the Company announced the successful pre-clinical and clinical CelGro® nerve repair study results showing superior nerve regeneration and consistent restoration of upper limb function in people with tetraplegia were presented at the 50th West Australian Branch Australian Orthopaedic Association (AOA) annual scientific meeting. Australian orthopaedic nerve specialist and clinical trial lead, Dr Alex O'Beirne presented the results of two successful CelGro® nerve repair studies titled: "Development of an epineurial substitute for nerve repair in patients with tetraplegia: proof of concept pre-clinical and clinical studies". The CelGro® nerve product has now been named Remplir™.

Dr Alex O'Beirne highlighted:

- In the pre-clinical study, **sciatic nerves in rats repaired with** Remplir™ **exhibited no inflammation, scar tissue formation or fibro-adhesions**. Remplir™ integrated into the host epineurium (outer layer of connective tissue of the nerve), was remodelled into natural tissue, and at 4 weeks post treatment, resembled the native sciatic nerve in appearance. For full study results, **click here**;
- In the Remplir™ nerve regeneration clinical study, seventeen nerve repairs were performed with Remplir™ in five quadriplegic patients. Patients demonstrated faster and better results in muscle function restoration, compared to published studies of nerve transfer surgery using the standard method (direct suture). In particular, **76.5% of the tetraplegic nerve transfers (13 of 17) resulted in the best-case clinical outcome (MRC Grade 3 or 4[1])** at 12 months post treatment. An MRC Grade 3 or 4 means quadriplegic patients regain a level of independence, enabling them to perform tasks such as brushing teeth, drinking from a cup, and transferring into and out of a wheelchair without assistance. For full study results, **click here**;

The Company continues to work closely with the Experien Group, headquartered in Silicon Valley as the Company's US regulatory advisers to evaluate opportunities for expedited approval of Remplir™

for nerve regeneration. The team is now finalising the 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.

3. CelGro® Pipeline

CelGro® collagen rope for Anterior Cruciate Ligament reconstruction

The Company completed its pre-clinical Anterior Cruciate Ligament (ACL) reconstruction study in September 2021, which indicated that a novel CelGro® collagen 'rope' has potential to be the first off-the-shelf biological device capable of improving ACL reconstruction outcomes. Top line data included:

- CelGro® collagen rope promoted ligamentisation and exhibited tissue architecture that mimics native ACL
- CelGro® collagen rope integrated with the host bone tunnel and was biomechanically comparable to hamstring tendon autograft
- Results position CelGro® collagen rope as the potential first off-the-shelf biological device for ACL reconstruction

In light of these results, Orthocell plans to advance development of this technology and will commence a larger animal study followed by first-in-human trials.

CelGro® seeded with cells to create functional tissue

The Company announced the publication of a breakthrough tissue engineering study ("study") combining CelGro® with lymphatic and blood vessel cells to create functional lymphatic tissue in August 2021. The findings represent a substantial advance in the *ex vivo* fabrication of implantable lymphatic grafts and their use in novel surgical treatments for patients suffering from 'Lymphedema' (swelling of the arm or leg caused by lymphatic system blockage often caused by lymph node removal or damage due to cancer treatment).

The novel study was published in Proceedings of the National Academy of Sciences of the United States of America ("PNAS"), a highly regarded peer-reviewed scientific journal. The publication follows a successful collaboration between Professor Shulamit Levenberg at the Israel Institute of Technology and Orthocell's inventor and Chief Scientific Officer, Professor Minghao Zheng at the Perron Institute and the University of Western Australia. The publication may be viewed here.

This exciting research opens up potential for novel treatments addressing significant unmet medical needs in women's health and the Company will explore these development options alongside its nerve repair applications. CelGro® continues to impress and this further validates the very valuable CelGro® platform technology addressing multiple medical needs.

ortho·cell
advancing tissue repair & regeneration

Intellectual Property

During the quarter the Company announced it has been granted additional patents for its novel CelGro® collagen medical device platform for soft tissue regeneration applications. In particular, Canada and Hong Kong patents granted for sutureless repair of soft tissue covering the method of using CelGro® to repair a defect in soft tissue, such as tendons, ligaments and nerves, avoiding the use of damaging sutures. The patents are also approved in Australia, New Zealand, China and Japan, with further applications progressing in US and EU.

Corporate

Orthocell's net operating cash outflows for the quarter were A$1,930k. 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$14.6m.

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:

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 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 (Ortho-ATI®) and Autologous Chondrocyte Implantation (Ortho-ACI®), which aim to regenerate damaged tendon and cartilage tissue. Orthocell is moving forward with clinical studies for Ortho-ATI® 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 September 2021

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	356	356
1.2	Payments for:		
	(a) research & development (including allocated staff costs)	(1,502)	(1,502)
	(b) patent & trademark fees	(151)	(151)
	(c) marketing, business development & investor relations	(102)	(102)
	(d) leased assets	(1)	(1)
	(e) staff costs (other than R&D staff)	(255)	(255)
	(f) administration & corporate costs	(279)	(279)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	4	4
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**	**(1,930)**	**(1,930)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant & equipment	(15)	(15)
	(d) investments	-	-
	(e) intellectual property	-	-
	(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**	**(15)**	**(15)**

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	235	235
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**	**235**	**235**

4.	**Net increase / (decrease) in cash & cash equivalents for the period**		
4.1	Cash & cash equivalents at beginning of period	16,329	16,329
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,930)	(1,930)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(15)	(15)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	235	235
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash & cash equivalents at end of period**	**14,619**	**14,619**

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	1,419	1,329
5.2	Term deposits	13,200	15,000
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)**	**14,619**	**16,329**

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	399
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)	(1,930)
8.2	Cash and cash equivalents at quarter end (item 4.6)	14,619
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	14,619
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**8**

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-Oct-21

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.