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Quarterly Report – September 2020

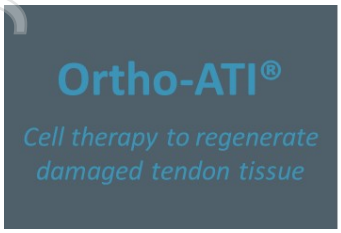
Perth, Australia – 29 October 2020: Orthocell Limited (ASX: OCC, "Orthocell" or "the Company") is pleased to release its Quarterly Report for the quarter ended 30 September 2020.

Key highlights for the quarter:

- **Ortho-ATI® for rotator cuff tendon injury clinical study is fully recruited and on track to report top line data in 3Q CY 2021**
- **Positive results of CelGro® in guided bone regeneration studies published in the highly regarded journal 'Tissue Engineering'**
- **AUS TGA's evaluation of the CelGro® market authorisation application (for dental bone and soft tissue regeneration applications) progressing as planned**
- **Transition from supplying CelGro® under Special Access Scheme (SAS) category "B" to SAS category "C" underpins the growing safety and efficacy profile of the CelGro® platform device**
- **Over 300 patients treated with CelGro® under Special Access Scheme (SAS)** via approvals granted by the TGA for use of CelGro® in nerve, tendon, cartilage and dental maxillofacial bone repair
- **Australian TGA regulatory application for CelGro® for peripheral nerve repair surgical applications submitted -** follows positive results from Orthocell's nerve repair study, showing 96% of nerve repairs restored voluntary movement in affected muscles
- **First round of questions from the US FDA regarding the market authorisation application for CelGro® in bone and soft tissue regeneration applications received**
- **87.5% patient satisfaction rating using Ortho-ATI® cell therapy** for the treatment of chronic tendon injuries of the shoulder and a 74.3% patient satisfaction rating for all indications combined.

Orthocell Managing Director, Paul Anderson said: "Orthocell is in a strong and unique position internationally with a confluence of near term clinical data read outs and regulatory approvals in target jurisdictions for its portfolio of leading regenerative medicine products. We are in an exciting phase, and set to continue to grow the value of individual product segments and importantly grow the value of the company."

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Ortho-ATI®

Ortho-ATI® is a world-leading breakthrough in regenerative medicine – a novel cell therapy developed to treat chronic degenerative tendon injuries (tendinopathy / tendonitis). The Company is currently conducting two clinical trials with Ortho-ATI®, the first is focused on rotator cuff and the second on tennis elbow tendon defects. The rotator cuff study is fully recruited and is on track to provide a final data read out in 3Q CY2021. This will be the world's first randomised, active controlled clinical trial of a tendon regeneration cell therapy and represents a significant inflection point for the Company on its pathway to US approval and commercialisation. The tennis elbow study is 70% recruited and plans to be fully recruited in CY 2021.

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.

US FDA clinical development plan and regulatory pathway

During the quarter, the Company continued to work with Greenleaf Health ("Greenleaf"), a US based specialist regulatory consulting firm with particular expertise in cell and gene therapy product development and US FDA regulatory submissions and interactions. Greenleaf were engaged to review the Company's clinical development plan and the draft US study protocol required to progress commercialisation in the US and assess the applicability of Ortho-ATI® for FDA expedited programs and priority review designations.

Successful Annual Quality Survey

As part of Orthocell's commitment to its continuous delivery of high quality regenerative medicine products, the Company administers an Annual Quality Study ("AQS") to capture patient feedback following treatment of chronic tendon injuries with Orthocell's Ortho-ATI® cellular therapy.

On the 9th July, the Company announced the results from its 2019 AQS and trends since 2015. Summary results included:

- 87.5% satisfaction in patients who received Ortho-ATI® tendon repair treatment, in the shoulder, in the four AQS surveys conducted between 2015 and 2019
- 74.2% satisfaction in patients who received Ortho-ATI® tendon repair treatment in the four AQS surveys conducted between 2015 and 2019
- 2019 AQS included treatment of six (6) different anatomical locations (tendons) including Elbow (56%), Shoulder (18%), Hip (13%), Knee (3%) Achilles/ankle/foot (10%)

1. US, Japanese, European and Australian markets

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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$4.4bn[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.

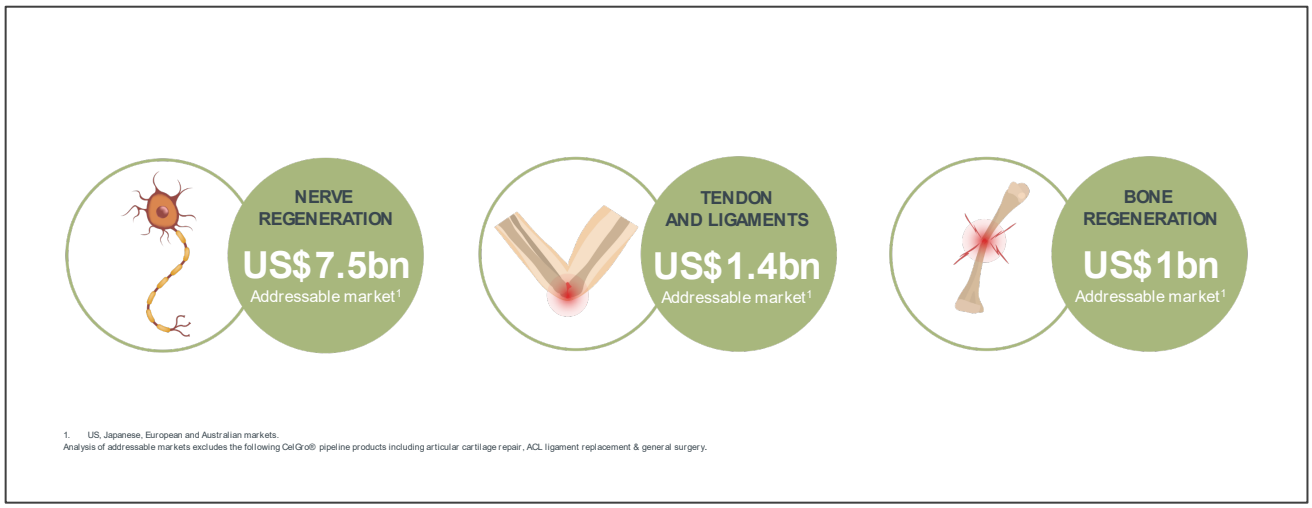


Figure 1: CelGro® Platform Technology

Supply of CelGro under special access scheme category "C"

During the Quarter, Orthocell was advised by the Therapeutic Goods Administration (TGA) that the Company can transition from supplying CelGro® under Special Access Scheme (SAS) category "B" to SAS category "C" for ACI (knee and ankle) and rotator cuff tendon repair. Transitioning from category "B" to category "C" means that pre-approval from the TGA is no longer required for those indications, as long as the prescriber is an orthopaedic surgeon. The surgeon is now able to complete cartilage and tendon repairs using CelGro® and notify the TGA within 28 days post treatment, rather than requesting approval from the TGA prior to use. This is positive news that underpins the growing safety and efficacy profile of the CelGro® platform device and supports the current "in progress" regulatory submission to the TGA in Australia for approval to market CelGro® for dental bone and soft tissue regeneration applications.

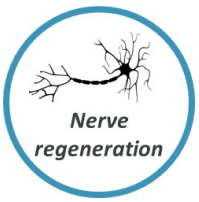
CelGro® reaches 300-case milestone under SAS

CelGro® reached the 300-case milestone under SAS during the quarter. Approvals were granted by the TGA for use of CelGro® in nerve, tendon, cartilage and dental maxillofacial bone repair. The SAS provides surgeons and patients access to therapeutic goods with significant advantages over existing products prior

1. US, Japanese, European and Australian markets

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to regulatory approval. SAS product use provides real-world evidence for the safety and efficacy of CelGro®, further validating data collected in clinical trials.



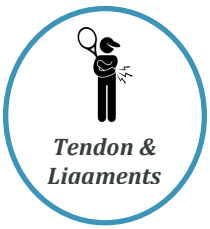
1. CelGro® Nerve Regeneration

During the quarter, the company announced submission of its Australian TGA regulatory application for CelGro® for peripheral nerve repair surgical applications. This follows positive results from Orthocell's nerve repair study, showing 96% of nerve repairs restored voluntary movement in affected muscles. The recent study showed that at 12 months after CelGro® surgery, voluntary muscle movement was restored in 96% of nerve repairs; and 86% of patients who required prescription pain medication, including opioid-based medications, were able to significantly reduce or stop their medication completely.

CelGro®'s addressable market in nerve repair is estimated to be worth more than US$7.5 billion[1] per annum. Marketing and sale of CelGro® for nerve repair applications in Australia can commence post TGA regulatory approval.

Orthocell continues to progress the CelGro® nerve regeneration trial with one patient remaining to complete recruitment to the 20 patient study. Whilst COVID-19 restrictions have impacted timeframes to complete recruitment to the study, the Company remains focused on finalising this trial and leveraging the data for commercialisation in AUS and the US.

Commencement of the US regulatory study to support a US 510(k) submission for clearance to market CelGro® for peripheral nerve regeneration applications (which is the current proposed approval pathway), was delayed during the quarter due to COVID-19 restrictions. The Company has been advised, with the easing of restrictions in undertaking research at the University of Western Sydney, surgical procedures can likely re-commence in early November 2020. The Company will notify the ASX when surgical procedures re-commence and will be reviewing the preferred approval pathway accordingly.



2. CelGro® Tendon and Ligament Regeneration

Orthocell has progressed implementation of its regulatory strategy to achieve US and AUS approval to market CelGro® for tendon repair procedures. The regulatory and research team is continuing to work on the US study design and to prepare for a US FDA pre-submission meeting. The team is also collating additional clinical evidence relating to the positive performance of CelGro® in augmenting tendon repair for the TGA submission. Whilst COVID-19 restrictions have impacted timeframes to collate this data, the team remains focussed on finalising the TGA submission in Q4 CY2020 or soon after.

1. US, Japanese, European and Australian markets

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3. CelGro® Bone and soft tissue repair

The CelGro® dental product is in a regulatory phase with EU approval in place and AUS and US submissions in progress. Key market approvals are an essential factor in securing a strategic partner to manage the distribution and marketing of CelGro® for dental bone and soft tissue repair procedures. With scalable manufacturing in key market approvals in progress, and industry leading brand ambassadors using the product, Orthocell is well positioned to execute on its partnering and commercialisation strategy.

Expanding target market regulatory approvals

United States

In the previous quarter Orthocell announced submission to the US Food and Drug Administration (FDA) seeking 510(k) clearance for marketing its CelGro® product for dental guided bone and soft tissue regeneration applications. During the quarter, Orthocell received the first round of questions from the FDA regarding the US market authorisation application. The FDA requested further information on the device composition, description and other administrative matters such as labelling. The Company is pleased with the questions received as they largely relate to administrative matters and not related to product performance. The Orthocell team is currently compiling responses to the FDA questions and continues to work towards US 510(k) clearance.

Australia

The US 510(k) submission compliments Orthocell's current "in progress" regulatory submission to the TGA in Australia for approval to market CelGro® for dental bone and soft tissue regeneration applications. During the quarter, the Company held further progress discussions with the TGA regarding its submission and remains on track for Australian market approval in CY 2020. The Company is now finalising plans for introduction to the Australian market and to grow product awareness and use in key accounts.

Growing the body of clinical evidence

During the quarter, the company announced the publication of positive pre-clinical and clinical results for the use of CelGro® in enhancing repair of critical bone defects in the highly regarded "Tissue Engineering" Journal. The paper is entitled "Collagen Membrane for Guided Bone Regeneration in Dental and Orthopaedic Applications". A copy of the publication can be found here: CelGro GBR Publication. Accelerated repair of critical bone defects represents an area of significant clinical interest to the dental and orthopaedic community. Orthocell intends to leverage CelGro®'s ability to guide superior quality bone formation to further position CelGro® as the best-in-class collagen membrane for bone and soft tissue repair.

Increasing product awareness and use in centres of excellence

During the quarter, COVID-19 restrictions in the EU and the UK prevented most dental practices from treating patients. In response to these restrictions and the current dental market conditions, the

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Company has placed various promotional and distribution personnel related expenses on hold until dental surgeons are able to return to the regular treatment of patients. The Company is utilising this period to prepare for the anticipated return of demand for high quality products, such as CelGro®, to facilitate rapid and high quality dental procedures by continuing to invest in its clinician advocacy program and a digital marketing campaign to grow product awareness and use in centres of excellence.

Video conferences were held in place of in person meetings due to COVID-19 restrictions and were effective in maintaining contact and continued development of strategic relationships with industry leading clinicians in the US, UK, Spain, France and Italy.

Corporate

The Company released a comprehensive update of Orthocell's regenerative medicine product portfolio, including a summary of key clinical, regulatory and commercial milestones. This included delivering a series of investor presentations and participating in media interviews. The presentation can be viewed in the investors section of the Company's website www.orthocell.com.au.

Orthocell's net operating cash outflows for the quarter were A$1.5m, with the majority of expenditure allocated to commercial and R&D related activities. At the end of the quarter, Orthocell held a cash balance of A$18.9m.

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.

Corporate Governance Statement Amendment

The Company advises that it has amended the responses to Recommendations 2.3 and 2.4 in the Corporate Governance Statement which was included in its 2020 Annual Report in relation to the composition of the Board.

The amended Corporate Governance documents are available in the investors section of the Company's website www.orthocell.com.au

Release authorised by:

Paul Anderson

Managing Director, Orthocell Limited

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For more information, please contact:

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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 soft tissue injuries. Orthocell's portfolio of products include CelGro® platform technology, a collagen medical device which facilitates tissue repair and healing in a variety of orthopaedic, reconstructive and surgical applications. Orthocell has received European regulatory approval (CE Mark) for CelGro® and is marketed within the European Union for a range of dental bone and soft tissue regeneration procedures. CelGro® is being readied for first approval in the US and AUS. The Company's other major focus is TGA-licensed 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 designed to assist in the US (FDA) approval process and has completed its pre-IND meetings with the FDA.

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

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Name of entity

Orthocell limited

ABN	**Quarter ended ("current quarter")**
57 118 897 135	30 September 2020

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		
1.2	Payments for:	179	179
	(a) research & development (including allocated staff costs)	(1,401)	(1,401)
	(b) patent & trademark fees	(102)	(102)
	(c) marketing, business development & investor relations	(88)	(88)
	(d) leased assets	(1)	(1)
	(e) staff costs (other than R&D staff)	(159)	(159)
	(f) administration & corporate costs	(197)	(197)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	1	1
1.5	Interest & other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants & tax incentives received	262	262
1.8	Other	-	-
1.9	**Net cash from / (used in) operating activities**	**(1,506)**	**(1,506)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant & equipment	(23)	(23)
	(d) investments	-	-
	(e) intellectual property	(2)	(2)
	(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**	**(25)**	**(25)**

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	22	22
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**	**22**	**22**

4.	**Net increase / (decrease) in cash & cash equivalents for the period**		
4.1	Cash & cash equivalents at beginning of period	20,442	20,442
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,506)	(1,506)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(25)	(25)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	22	22
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash & cash equivalents at end of period**	**18,933**	**18,933**

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	3,933	5,442
5.2	Term deposits	15,000	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)**	**18,933**	**20,442**

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	383
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.

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8.	Estimated cash available for future operating activities	$A'000s
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,506)
8.2	Cash and cash equivalents at quarter end (item 4.6)	18,933
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	18,933
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**13**

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-20

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.

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