ortho·cell
advancing tissue repair & regeneration

Quarterly Report – March 2021

Perth, Australia – 30 April 2021: Orthocell Limited (ASX: OCC, "Orthocell" or "the Company") is pleased to release its Quarterly Report for the quarter ended 31 March 2021.

Key highlights for the quarter:

- **Orthocell received US FDA 510(k) clearance to market and supply Striate+™** for dental bone and tissue regeneration procedures in the US dental market
- **Striate+ granted inclusion on the Australian Prostheses List allowing dental practitioners to receive reimbursement from private insurers** for use of Striate+ in approved dental bone and soft tissue repair procedures, reducing costs to the patient
- **Engaged Seattle Study Club as a key global Striate+ education and promotion partner**
- **US 510(k) pilot animal study results indicate CelGro® facilitates superior nerve regeneration when compared to the market leading nerve repair device**, restoring the sciatic nerve to its pre-injured state with no adverse reactions (post quarter end)
- **Granted a new US divisional patent for CelGro® entitled "Method for producing a collagen membrane and uses thereof"**
- **Publication of a successful case study focusing on the combination of CelGro® and autologous tenocyte implantation ("Ortho-ATI®")** for the surgical repair of a large degenerate tear of the gluteal medius (hip) tendon
- **Orthocell received A$2,394,397 R&D tax incentive refund**

Orthocell Managing Director, Paul Anderson said: "This has been a tremendous quarter for the Company. We have achieved significant milestones in the commercialisation of Striate+, the first on-market product from our CelGro® platform technology. I am excited by the potential of our Australian invented and manufactured product, and the progress of our broader team in preparing for entry into the Australian and significant US market."

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.

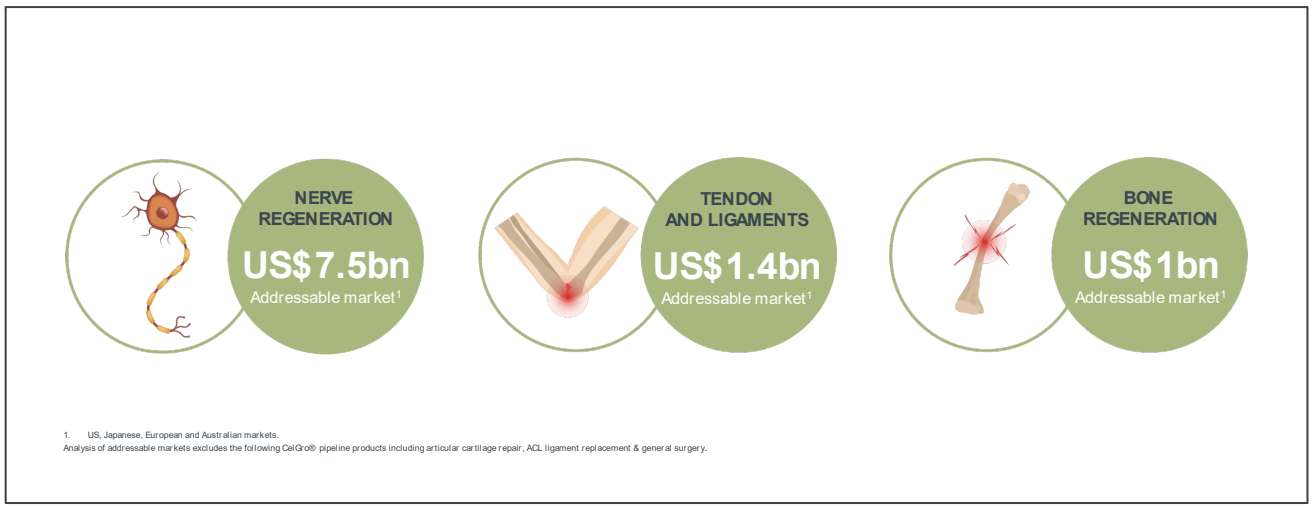


Figure 1: CelGro® Platform Technology

1. Striate+ for dental bone and tissue repair

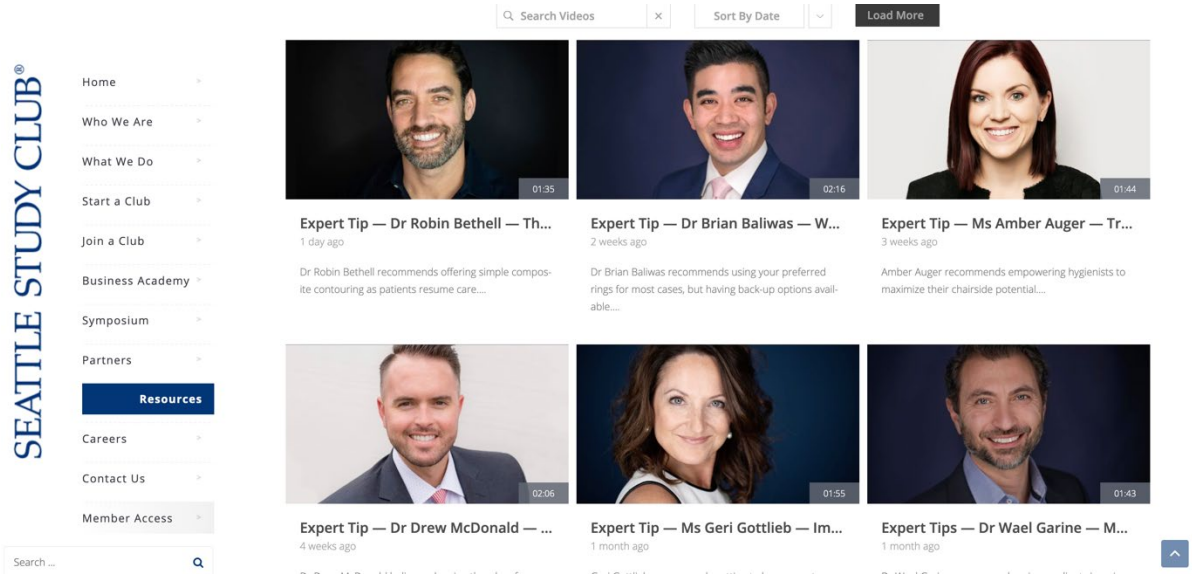
Orthocell has successfully completed the regulatory phase for use of Striate+™ (previously branded as CelGro® Dental) in dental bone and soft tissue repair procedures, successfully attaining AUS, US and EU approval. Key market approvals and key opinion leader product use are essential factors in securing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

During the quarter Orthocell received FDA 510(k) clearance 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]. The 510(k) clearance follows the Company's application submitted to the FDA in May 2020.

Since gaining US market approval the Company has focused on preparing for market entry, including the incorporation of a Delaware limited liability company to supply product in the US, evaluating high quality warehouse and logistics providers, establishing a US focused website and the engagement of Seattle Study Club (SSC) as a key global Striate+ education and promotion partner.

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 network includes 260 clubs, with significant representation in Orthocell's key markets - US, EU/UK, and AUS. Each club meets regularly for interactive educational programs, discussion on the latest developments in dentistry, and presentations by world-renowned clinical speakers. These meetings provide a forum for Orthocell to grow awareness of Striate+ through targeted education and to establish key accounts with high quality dental clinicians.



Importantly, the SSC partnership provides Orthocell with:

- Six additional US key influencers who are clinically respected surgeons with extensive social media followings to become Striate+ product advocates, present Striate+ cases studies at congresses, and promote to and influence other SSC directors and their peers;
- development of key influencer videos sharing "tips and tricks" on how Striate+ has improved their patient experience – less or improved healing time, increased cortical bone, handling characteristics, how it has helped them chairside, or other benefits;
- access to the online SSC journal to contribute articles, case studies, videos, and other educational based content;
- access to a database of over 5,700 clinicians to distribute educational material, lead generation campaigns and promotional offers; and
- participation in the invitation only annual SSC congress attended by leading Dental companies and clinicians.

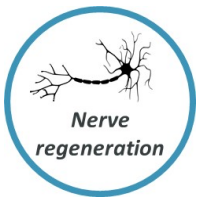
The Company looks forward to working with the SSC and preparing for market entry to the significant and rapidly growing US dental market.

Australian Market

The Company received notification from the Australian Government Department of Health that CelGro® Dental has been included on the Australian Prostheses List. This enables dental practitioners to receive reimbursement from private insurers for its use in approved dental bone and soft tissue repair procedures, reducing costs to the patient. Australian reimbursement followed market approval announced 23 December 2020. Since receiving reimbursement approval, the Company has been actively preparing for WA market entry, establishing key opinion leader accounts, engaging public/teaching hospitals, private hospitals and corporatised dental practices and evaluating potential distributors.

UK and EU Market

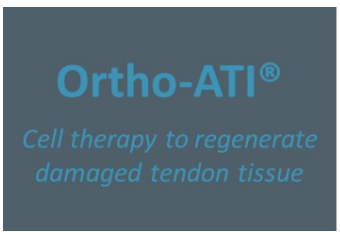
During the quarter, new strains of COVID-19 and subsequent social distancing restrictions in the EU and the UK prevented most dental practices from treating patients. In response to these restrictions and the current dental market conditions, the Company has placed various promotional and distribution 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 Striate+, to facilitate rapid and high quality dental procedures by continuing to invest in its clinician advocacy program and targeted digital marketing program. In particular, the Company sponsored surgical workshops in Spain, Greece and Poland, and released a series of webinars by Dr Nick Fahey and Prof. Massimo Simion highlighting the improved healing time, increased cortical bone and handling characteristics when using Striate+.



2. CelGro® Nerve Regeneration

Subsequent to the quarter end, Orthocell announced positive results from the US 510(k) animal pilot study, indicating that CelGro® facilitates superior nerve regeneration when compared to the market leading nerve repair device - restoring the sciatic nerve to a pre-injured state. These results combined with the previously released interim human clinical data, position CelGro® as the potential market leader in nerve regeneration and restoration of voluntary muscle control in patients with tetraplegia or paralysed upper limbs.

In light of these results, the Company is evaluating opportunities for expedited approval of CelGro® and following finalisation of the CelGro® nerve regeneration human clinical study in Q2 2021, will engage with the FDA to determine whether an expedited regulatory approval is possible and what this will mean for reimbursement value for the product.



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 80% 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.

Novel Surgical Treatment for Tendon Repair

The Company announced the publication of a successful case study focusing on the combination of CelGro® collagen medical device and autologous tenocyte implantation ("Ortho-ATI®") for the surgical repair of a large degenerate tear of the gluteal medius tendon. The case study was published by internationally recognised orthopaedic hip specialist surgeon Dr John M O'Donnell and sports and exercise doctor A/Professor Jane Fitzpatrick. The case report supports Ortho-ATI® and CelGro® as durable, long term solutions for degenerate, treatment resistant tendons that can be used on their own or in combination. The case report may be viewed here: Gluteal Tendon Regeneration Publication.

Intellectual Property

During the quarter the Company announced it has been granted a new US divisional patent for CelGro®. The patents entitled **"Method for Producing a Collagen Membrane and Uses Thereof"** provides additional important intellectual property (IP) to protect the CelGro® platform for soft tissue regeneration and repair applications expiring in June 2033. This is an important patent that further protects and strengthens the IP position for CelGro® providing greater layers of protection. Orthocell has secured 11 patent families covering its portfolio of breakthrough regenerative medicine products, comprising 110 separate patents/applications, of which 75 are granted.

Corporate

Orthocell's net operating cash inflows for the quarter were A$171k, inclusive of a A$2,394,397 R&D tax incentive refund. 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$17.77m.

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:

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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 (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	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	206	603
1.2	Payments for:		
	(a) research & development (including allocated staff costs)	(1,651)	(4,590)
	(b) patent & trademark fees	(129)	(279)
	(c) marketing, business development & investor relations	(123)	(321)
	(d) leased assets	(1)	(2)
	(e) staff costs (other than R&D staff)	(142)	(427)
	(f) administration & corporate costs	(391)	(749)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	8	199
1.5	Interest & other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants & tax incentives received	2,394	2,748
1.8	Other	-	-
1.9	**Net cash from / (used in) operating activities**	**171**	**(2,818)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant & equipment	(44)	(96)
	(d) investments	(21)	(33)
	(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**	**(65)**	**(129)**

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	99	271
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**	**99**	**271**

4.	**Net increase / (decrease) in cash & cash equivalents for the period**		
4.1	Cash & cash equivalents at beginning of period	17,561	20,442
4.2	Net cash from / (used in) operating activities (item 1.9 above)	171	(2,818)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(65)	(129)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	99	271
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash & cash equivalents at end of period**	**17,766**	**17,766**

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	1,766	2,411
5.2	Term deposits	16,000	15,000
5.3	Bank overdrafts	-	-
5.4	Other (subscription funds held in trust)	-	150
5.5	**Cash & cash equivalents at the end of the quarter (should equal item 4.6 above)**	**17,766**	**17,561**

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	225
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)	171
8.2	Cash and cash equivalents at quarter end (item 4.6)	17,766
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	17,766
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: 30-Apr-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.