ortho·cell
advancing tissue repair & regeneration

Quarterly Report – December 2020

Perth, Australia – 29 January 2021: Orthocell Limited (ASX: OCC, "Orthocell" or "the Company") is pleased to release its Quarterly Report for the quarter ended 31 December 2020.

Key highlights for the quarter:

- **Orthocell receives Australian TGA market approval to supply CelGro® in dental bone and tissue regeneration procedures**
- **Orthocell receives first US FDA CelGro® product approval in dental bone and tissue regeneration procedures (subsequent to quarter end)**
- **Positive long term clinical data shows nerve repair with CelGro® results in predictable and consistent restoration of upper limb function in Quadriplegic patients** - patient enrolment for the CelGro® nerve regeneration trial is complete
- **Orthocell received A$2,394,397 R&D tax incentive refund (subsequent to quarter end)**

Orthocell Managing Director, Paul Anderson said: "We are delighted to reach the important milestone and significant inflection point of gaining approval for CelGro® in US and AUS for dental Guided Bone Repair indications. I am excited by these positive steps in our pathway to partnering Striate+, the first product from the CelGro® platform technology. We are set to continue to grow the value of individual product segments within the significant bone, nerve and tendon markets."

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.

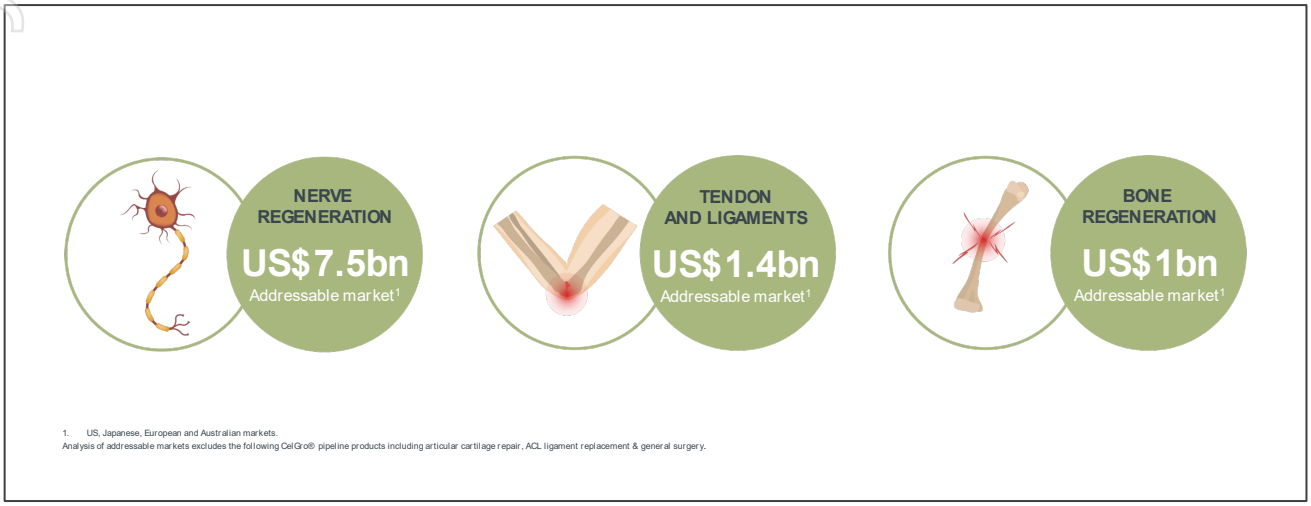


Figure 1: CelGro® Platform Technology

1. CelGro® Bone and soft 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 an essential factor 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. Striate+ has, based on surgeon feedback, distinct advantages over other similar products and may assist surgeons to deliver improved patient outcomes through superior handling characteristics, tissue integration qualities and improved bone healing. On the back of the recent FDA and TGA approvals, the Company is now finalising plans for introduction to the Australian and US market to grow product awareness and use in key accounts.

Expanding target market regulatory approvals

Australia

During the quarter Orthocell announced Australian market approval for its CelGro® collagen medical device, for introduction into the Australian dental bone and tissue regeneration market.

Inclusion of CelGro® Dental in the Australian Register of Therapeutic Goods (ARTG) follows the recent announcement on 17th December 2020 confirming the TGA completed its review of the Company's regulatory application and that Orthocell successfully demonstrated compliance with the requirements of the Medical Device Regulations (Conformity Assessment) with respect to the safety and performance of CelGro® in dental bone and tissue regeneration procedures.

The Company is now focused on achieving reimbursement by insurers and has progressed its application to the Prostheses List Advisory Committee for inclusion on the Prostheses List ("PL"). Inclusion on the PL may be finalised by Q2 CY2021.

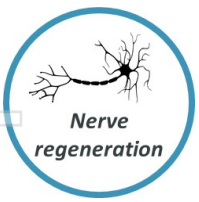
United States

Subsequent to quarter end, Orthocell received FDA 510(k) clearance to market and supply its CelGro collagen medical device for dental bone and tissue regeneration procedures. The FDA 510(k) clearance now allows Orthocell to supply Striate+ (previously branded as CelGro® Dental) in the US dental market, estimated at US$500 million per annum[1]. Striate+ has been approved for supply in dental bone and tissue regeneration procedures such as dental bone defect repair, augmentation around dental implants in immediate and delayed extraction sockets and guided tissue regeneration procedures in intrabone periodontal defects. The 510(k) clearance follows the Company's application submitted to the FDA in May 2020.

UK and EU

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 CelGro®, to facilitate rapid and high quality dental procedures by continuing to invest in its clinician advocacy program and a digital marketing campaign, including release of the first of a series of webinars 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.



2. CelGro® Nerve Regeneration

During the quarter Orthocell announced further positive long term clinical data showing nerve repair with CelGro® results in predictable and consistent restoration of upper limb function in Quadriplegic patients. The Company also announced it had decided, in consultations with key stakeholders, that the clinical results have met the study objectives and has closed recruitment early. Orthocell Managing Director Paul Anderson, said "Following these positive results validating the interim data, our team is progressing regulatory applications in the Australia and will commence the US regulatory study shortly to make this treatment accessible to the millions of people who experience nerve damage annually."

Positive 24 month clinical data

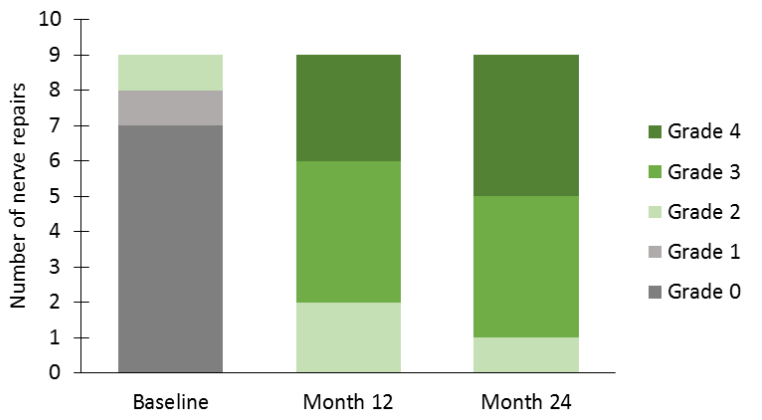
The Company announced further clinical results from ten participants (involving 19 nerve repairs) 24 months after treatment with CelGro® showing upper limb function was restored in 17 of 19 (89%) nerve repairs. These positive results follow the interim data announced on 9 October 2019 showing patients ceased, or significantly reduced, prescription pain medication (including opioid-based medications), and in many cases returned to work and participation in recreational activities.

Patients in the clinical trial received one or several nerve repairs augmented with CelGro® in one or both upper limbs. Patients experienced significant pain and were unable to perform basic activities of daily living (e.g. eating, bathing, dressing and toileting), playing sport and/or working. They would not have regained normal use of their injured arm and hand without surgery.

A review of the quadriplegic patient cohort contributing 12 and 24-month data after treatment, involving nine nerve transfers augmented with CelGro® showed:

- **Quadriplegic patients regained voluntary muscle movement of previously impaired or paralysed upper limbs within 12 months** (MRC Grade 2 or better)**Error! Bookmark not defined.** of treatment (see figure 1).
- **Number of nerve repairs resulting in the best case clinical outcome (MRC Grade 3 or 4) increased from 7 of 9 (78%)** repairs at 12 months **to 8 of 9 (89%)** repairs at 24 months post treatment.
- **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.

Figure 1 – Recovery of Muscle Power in Patients with Quadriplegia



Grade 3 and 4 – voluntary movement with improved strength and range of motion. **Maximum level of recovery expected.**

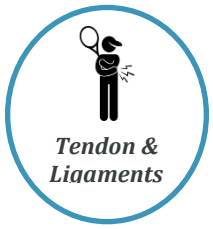
Grade 2 – voluntary movement restored, limited strength and range of movement.

Grade 0 or 1 – no voluntary movement.

The Company believes CelGro® to be an important step forward for improving nerve repair. Its ease of use, consistent and predictable high-quality outcomes, achieved in a shorter time, when compared to other methods, will empower surgeons to improve the lives of patients with these complex injuries.

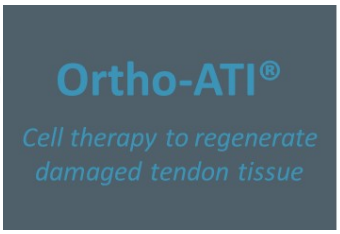
CelGro®'s addressable market in nerve repair is estimated to be worth more than US$7.5 billion[1] per annum. Marketing and sale of CelGro® for nerve repair applications in Australia can commence post TGA regulatory approval.

The Company is awaiting ethics approval to commence 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). Ethics approval is expected shortly and the Company will be reviewing the preferred approval pathway accordingly.



3. CelGro® Tendon and Ligament Regeneration

The Company has continued to progress the AUS and US product registration and commercialisation program for the CelGro® tendon repair medical device. During the Quarter the Company collated additional clinical evidence relating to the positive performance of CelGro® in augmenting tendon repair in preparation for the Australian TGA submission. Whilst COVID-19 restrictions have impacted timeframes to collate this data, the team remains focussed on finalising submission documents.



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.

Corporate

In January 2021 Orthocell received A$2,394,397 R&D tax incentive refund.

Orthocell's net operating cash outflows for the quarter were A$1.48m, 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$17.56m.

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
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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®, a collagen medical device which facilitates tissue repair and healing in a variety of dental, nerve and orthopaedic, reconstructive applications. Orthocell recently received FDA 510(k) approval for Striate+, the first application of the CelGro® platform for dental GBR applications. Striate+ is also approved in Australia (ARTG) and Europe (CE Mark) for the same. The Company's other major products are the cell therapies Autologous Tenocyte Implantation (Ortho-ATI®) and Autologous Chondrocyte Implantation (Ortho-ACI®), which aim to regenerate damaged tendon and cartilage tissue respectively. Orthocell is moving forward with Ortho-ATI® 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

Name of entity

Orthocell limited

ABN	**Quarter ended ("current quarter")**
57 118 897 135	31 December 2020

Consolidated statement of cash flows		**Current quarter $A'000s**	**Year to date (6 months) $A'000s**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	218	397
1.2	Payments for:		
	(a) research & development (including allocated staff costs)	(1,489)	(2,888)
	(b) patent & trademark fees	(48)	(150)
	(c) marketing, business development & investor relations	(110)	(198)
	(d) leased assets	(1)	(1)
	(e) staff costs (other than R&D staff)	(175)	(334)
	(f) administration & corporate costs	(161)	(358)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	190	190
1.5	Interest & other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants & tax incentives received	93	354
1.8	Other	-	-
1.9	**Net cash from / (used in) operating activities**	**(1,483)**	**(2,988)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant & equipment	(29)	(52)
	(d) investments	-	-
	(e) intellectual property	(10)	(12)
	(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**	**(39)**	**(64)**

Consolidated statement of cash flows		Current quarter $A'000s	Year to date (6 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	150	172
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**	**150**	**172**

4.	**Net increase / (decrease) in cash & cash equivalents for the period**		
4.1	Cash & cash equivalents at beginning of period	18,934	20,442
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,483)	(2,988)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(39)	(64)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	150	172
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash & cash equivalents at end of period**	**17,562**	**17,562**

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	2,412	3,934
5.2	Term deposits	15,000	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)**	**17,562**	**18,934**

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	237
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)	(1,483)
8.2	Cash and cash equivalents at quarter end (item 4.6)	17,562
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	17,562
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**12**

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-Jan-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.