ortho·cell
advancing tissue repair & regeneration

Quarterly Report – December 2019

Perth, Australia; 31 January 2020: Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to release its Quarterly Report for the quarter ended 31 December 2019.

Key highlights for the quarter:

- **CelGro® interim clinical study results show 96% of nerve repairs restored voluntary movement** to previously paralysed muscles - **All quadriplegic patients** increased movement and power of affected muscles following CelGro® nerve regeneration treatment
- **FDA confirms CelGro® Nerve regeneration study** design meets US 510(k) submission requirements - US 510(k) study expected to commence Q1 CY2020
- **Company advances CelGro® regulatory program -** Australian submission under review by the TGA and market entry study for the FDA (US) submission progressed
- **United States patent** has been accepted for a potential breakthrough CelGro® collagen rope device to enhance the surgical repair of Anterior Cruciate Ligament injuries
- **Orthocell successfully completes placement and share purchase plan raising $14.4m** with demand for the placement well in excess of funds sought, and supported by existing shareholders, new institutions and other sophisticated investors.

Orthocell Managing Director Paul Anderson said: "This has been another outstanding period for the Company with the success of clinical studies further validating the effectiveness of CelGro® to enhance the repair of damaged nerves, bone and tendons. Orthocell is in a strong financial position and is well placed to accelerate its regulatory program, establish commercial infrastructure and execute on its partnering strategy delivering significant shareholder value in the near term."

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 (Figure 1: CelGro® Platform Technology). 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 realise multiple commercial partnering opportunities.

[1] US, Japanese, European and Australian markets

[2] Data presented at the American Academy of Orthopaedic Surgeons Annual Meeting in 2015

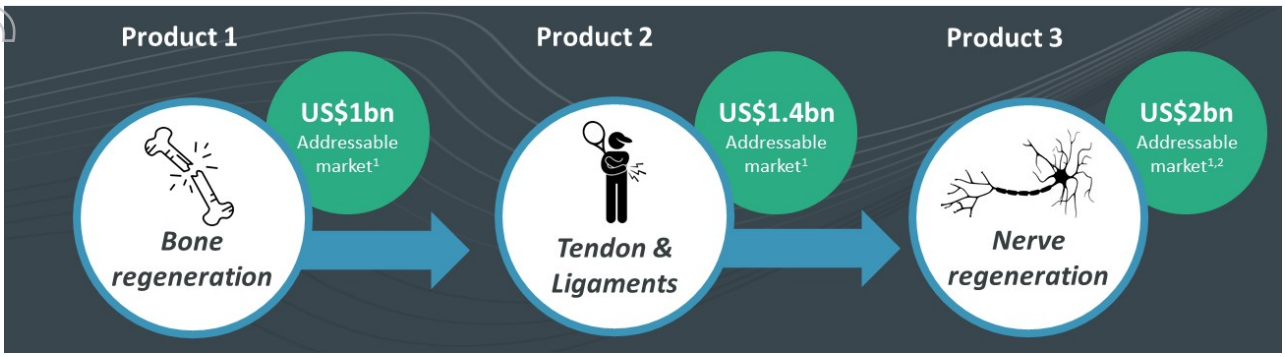
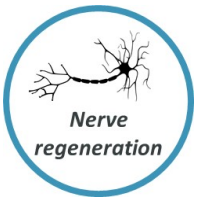


Figure 1: CelGro® Platform Technology



1. CelGro® Nerve Regeneration:

"Positive CelGro® nerve regeneration results in quadriplegic patients"

During the quarter, Orthocell announced interim clinical results for the use of CelGro® for enhancing repair of peripheral nerves of the first twelve (of twenty) study participants, 12 months after treatment, involving twenty-five nerve transfers. Participants had nerve injuries of varying severity, from peripheral nerve injury (3 patients), to more complex injuries of the brachial plexus and spinal cord (9 patients in total), resulting in impaired use of the affected limbs and in the more severe cases, quadriplegia. Results at 12 months after treatment with CelGro® included:

- **96% of nerve repairs restored voluntary movement** to previously paralysed muscles;
- **All quadriplegic patients increased movement and power of affected muscles** following CelGro® nerve regeneration treatment;
- **86% of patients** who required prescription medication (including opioid-based medications) for chronic nerve pain were able to **significantly reduce or cease their use;** and
- Nerve repair with **CelGro® resulted in predictable and consistent restoration of muscle function.**

Results showed that nerve repair using CelGro® resulted in improvements in muscle power at 12 months that were comparable to what would normally be expected at 24 months with other methods. The Company believes the consistent and predictable outcomes of nerve repair with CelGro®, achieved in a shorter time, will empower surgeons to improve the lives of patients with these complex injuries.

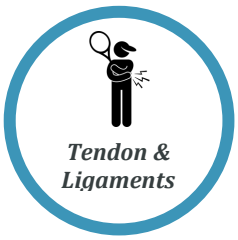
"US Nerve Repair Study Design Meets FDA Requirements"

Following the successful CelGro® nerve repair study results and growing demand from industry leading clinicians and potential partners for superior nerve repair medical devices, the Company commenced pre-submission activities with the FDA to confirm the requirements for US market approval. Feedback received during the quarter from the FDA confirmed the proposed CelGro® nerve regeneration animal study protocol was suitable to support an evaluation of substantial equivalence

[2] Data presented at the American Academy of Orthopaedic Surgeons Annual Meeting in 2015

to an approved nerve repair device, meeting the requirements of the US 510(k) predicate product regulatory pathway. The Company has now accelerated ethics applications to commence the study in Q1 CY2020.

Orthocell has a clear commercialisation strategy for the CelGro® nerve regeneration indication and is leveraging the recent clinical results and European approval of CelGro® to accelerate regulatory submission in the US, EU and Australia.



2. **CelGro® Tendon & Ligament repair: "Continuing potential partner discussions"**

In the previous quarter, the company announced final results from patients who completed the CelGro® tendon regeneration clinical trial. A clinical follow-up of trial participants at two years after surgery found all patients achieved a successful tendon repair. No patients required further surgery for a re-tear of the rotator cuff tendon – an important finding since revision surgeries for re-tears is reported to occur in up to 57%.[2] of cases.

During the quarter, the Company discussed these results with potential commercial partners and presented at key industry meetings including the 6th European College of Sports and Exercise Physicians meeting in Paris, the annual Australian & New Zealand Orthopaedic Society and the Australian Orthopaedic Association Conference in Canberra. The Company is leveraging the clinical data and intends to accelerate regulatory submissions for approval of the tendon repair product in the EU, AUS and the US.

CelGro® collagen rope – a potential breakthrough pipeline product for ligament repair

Orthocell has developed an alternative to tendon graft made from braided CelGro® collagen fibers for ACL reconstruction. The CelGro® collagen rope is designed to significantly improve treatment efficiency and effectiveness by simplifying repair techniques, reducing surgery time and mitigating the risks associated with harvesting the patient's hamstring tendon. During the quarter, the Company announced a United States patent has been accepted for a potential breakthrough CelGro® collagen rope device to enhance the surgical repair of Anterior Cruciate Ligament injuries. The patent entitled "**Collagen Construct and Method for Producing the Collagen Construct**" is now approved in Australia, Japan and the United States providing additional important intellectual property to protect the CelGro® platform for soft tissue regeneration and repair applications and expires on or after 12 October 2035.

The company is in the process of completing the pre-clinical study using CelGro® collagen rope for Anterior Cruciate Ligament (ACL) reconstruction and will provide a **full report of study results by 1Q CY2020.**

[2] Data presented at the American Academy of Orthopaedic Surgeons Annual Meeting in 2015

3. CelGro® Bone and soft tissue repair: "increasing product awareness and use in centres of excellence"

In the previous quarter, the Company presented the market leading CelGro® single-stage dental implant study results at key industry conferences in Lisbon and Dessau and engaged ten (10) industry leading clinicians (KOL's) based in the EU and the US to assist in rolling out the clinician advocacy program. During the quarter, the Company continued its clinician advocacy program to expand the network of referring clinicians and support discussions with strategic partners by meeting in person with the recently engaged KOL's, supplying CelGro® for use in their clinics and scheduling industry workshops, conference attendance and podium presentations for 2020 calendar year.

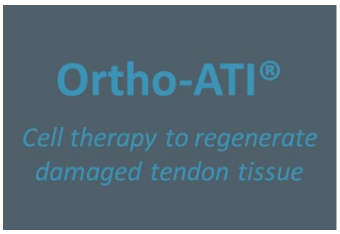
The Company is also supplying CelGro® to KOL's in the Australian market via the Special Access Scheme (SAS). The SAS is governed by the Therapeutic Goods Administration (TGA) and enables use of an unapproved therapeutic good for a single patient, on a case by case basis. CelGro® has been used via the SAS in over 120 surgeries in Australia to augment repair of dental bone defects, tendons, ligaments and cartilage.

Expanding target market regulatory approvals

During the quarter, Orthocell continued to progress the regulatory studies required for US marketing authorisation (510k clearance) and remains on track to submit an application to the FDA in the near term. In the previous quarter, The Company submitted its application to the TGA and currently remains on track to receive Australian marketing authorisation (ARTG) enabling the supply of CelGro® in dental guided bone and tissue regeneration in CY 2020.

Continuing partner discussions

The Company continues to progress discussions with potential global partners. With EU approval achieved, industry leading brand ambassadors appointed and a US market authorisation submission in development, Orthocell is well placed to execute on its commercial partnering strategy in the near term.



Ortho-ATI®: progressing our collaboration with Johnson & Johnson

Ortho-ATI® is a world-leading breakthrough in regenerative medicine – a novel 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[2] and growing.

[2] US, Japanese, European and Australian markets

[2] Data presented at the American Academy of Orthopaedic Surgeons Annual Meeting in 2015

The company continues to recruit suitable patients to the randomised controlled clinical trial of Ortho-ATI® versus corticosteroid injection. The objective of this study is to assess the safety and effectiveness of Ortho-ATI® compared to corticosteroid injection in the treatment of rotator cuff tendinopathy and tear. The trial is being undertaken in collaboration with DePuy Synthes Products, Inc., part of the Johnson & Johnson Medical Device Companies. The Company is focussed on completing this trial and providing study outcomes to its collaboration partner.

Corporate

Orthocell completed a placement of 26,000,000 ordinary shares at $0.50 per share to raise $13 million before costs. Demand for the placement was well in excess of funds sought with support from existing shareholders, new institutions and other sophisticated investors. Eligible shareholders were also provided the opportunity to subscribe for new Orthocell Shares, by way of a non-underwritten SPP, at the Placement price of A$0.50 per share (without incurring brokerage or transaction fees). The Company received acceptances for a total of 2,846,000 shares raising an additional $1,423,000.

Orthocell's net operating outflows for the quarter were A$2.3m, 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$20.8m.

Funds raised from the SPP and recently completed Placement will be used primarily to accelerate regulatory approvals and commercialisation of CelGro® for bone, tendon and nerve regeneration following recent successful clinical results and growing demand from industry leading clinicians and potential partners for superior regenerative medicine medical devices. In addition, funds raised will be utilised to advance the development and commercialization of Ortho-ATI®, support continued business development and marketing initiatives and for general working capital purposes as set out in the announcement made on 4 December 2019.

Outlook

Orthocell remains focused on executing its partnering strategy for CelGro® in dental bone and soft tissue repair. This includes increasing international product awareness, growing product use in centres of excellence and growing base of brand ambassadors led by its KOLs, designed to optimise shareholder value. Over the medium to long term, Orthocell intends to leverage the CE Mark to achieve AUS and US regulatory approvals and accelerate the introduction of the tendon and nerve indications, in parallel to the commercialisation of Ortho-ATI® and pipeline products.

Paul Anderson
Managing Director

[2] Data presented at the American Academy of Orthopaedic Surgeons Annual Meeting in 2015

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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 orthopaedic, reconstructive and surgical applications. Orthocell recently received European regulatory approval (CE Mark) for CelGro®. The collagen medical device can now be marketed and sold within the European Union for a range of dental bone and soft tissue regeneration procedures and is being readied for first approval in the US and AUS. The Company's other major product 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

[2] Data presented at the American Academy of Orthopaedic Surgeons Annual Meeting in 2015

Appendix 4C

Quarterly report for entities subject to Listing Rule 4.7B

Introduced 31/03/00, amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

Name of entity

Orthocell limited

ABN	**Quarter ended ("current quarter")**
57 118 897 135	31 December 2019

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	160	349
1.2	Payments for:		
	(a) research & development	(1,007)	(1,811)
	(b) product manufacture & operating costs	(140)	(305)
	(c) marketing, business development & investor relations	(265)	(422)
	(d) leased assets	(1)	(1)
	(e) staff costs (research & development, production, admin)	(868)	(1,608)
	(f) administration & corporate costs	(209)	(528)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	23	36
1.5	Interest & other costs of finance paid	-	(10)
1.6	Income taxes paid	-	-
1.7	Government grants & tax incentives	-	-
1.8	Other	-	-
1.9	**Net cash from / (used in) operating activities**	**(2,307)**	**(4,300)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) property, plant & equipment	(2)	(2)
	(b) businesses (see note 10)	-	-
	(c) investments	-	-
	(d) intellectual property	(211)	(273)
	(e) other non-current assets	-	-
	Proceeds from disposal of:		
	(a) property, plant & equipment	-	-
	(b) businesses (see note 10)	-	-
	(c) investments	-	-
	(d) intellectual property	-	-
	(e) 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)	(150)	(300)
2.6	**Net cash from (used in) investing activities**	**(363)**	**(575)**

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 issue of shares	14,423	14,423
3.2	Proceeds from issue of convertible notes	-	-
3.3	Proceeds from exercise of share options	384	668
3.4	Transaction costs related to issues of shares, convertible notes or options	(650)	(650)
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**	**14,157**	**14,441**

4.	**Net increase / (decrease) in cash & cash equivalents for the period**		
4.1	Cash & cash equivalents at beginning of quarter/year to date	9,315	11,236
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,307)	(4,300)
4.3	Net cash from (used in) investing activities (item 2.6 above)	(363)	(575)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	14,157	14,441
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash & cash equivalents at end of quarter**	**20,802**	**20,802**

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	16,802	3,315
5.2	Term deposits	4,000	6,000
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)**	**20,802**	**9,315**

6.	**Payments to directors of the entity & their associates**	Current quarter $A'000s
6.1	Aggregate amount of payments to these parties included in item 1.2	222
6.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	-

6.3 Include below any explanation necessary to understand the transactions included in items 6.1 & 6.2

Executive remuneration and non-executive director fees and consulting fees

7.	**Payments to related entities of the entity & their associates**	Current quarter $A'000s
7.1	Aggregate amount of payments to these parties included in item 1.2	-
7.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	-

7.3 Include below any explanation necessary to understand the transactions included in items 7.1 & 7.2

8.	**Financing facilities available** 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**
8.1	Loan facilities	-	-
8.2	Credit standby arrangements	-	-
8.3	Other (please specify)	-	-

8.4 Include 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 details of those facilities.

9.	**Estimated cash outflows for next quarter (excludes cash inflows)**	**$A'000s**
9.1	Research & development	1,100
9.2	Product manufacturing & operating costs	210
9.3	Marketing, business development & investor relations	300
9.4	Leased assets	1
9.5	Staff costs (research & development, production, administration)	820
9.6	Administration and corporate costs	360
9.7	Other (provide details if material)	-
9.8	**Total estimated cash outflows**	**2,791**

10.	**Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)**	**Acquisitions**	**Disposals**
10.1	Name of entity	-	-
10.2	Place of incorporation or registration	-	-
10.3	Consideration for acquisition or disposal	-	-
10.4	Total net assets	-	-
10.5	Nature of business	-	-

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.

Sign here: S H Roberston. Date: 31 January 2020

Print name: Simon Roberston

Notes

1 The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.

2 If this quarterly 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 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.