ortho·cell
advancing tissue repair & regeneration

Quarterly Report – September 2019

Perth, Australia; 31 October 2019: Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to release its Quarterly Report for the quarter ended 30 September 2019.

Key highlights for the quarter:

- **CelGro® study validates high quality nerve repair** facilitating regeneration of severed nerves returning them to normal nerve structure and avoiding the need to use multiple damaging sutures
- **CelGro® tendon regeneration clinical trial final results** showed that CelGro® guides and strengthens tendon healing when used in the surgical repair of the rotator cuff tendon in the shoulder, with 89% of patients returning to pain-free function
- **Company presents CelGro® dental implant data at** 28th Annual European Association for Osseointegration (EAO) scientific meeting
- **Company advances CelGro® bone and soft tissue repair regulatory program** with submission to the TGA (Australia) and progresses market entry study for the FDA (US) submission

Orthocell Managing Director Paul Anderson said: "This has been an outstanding period for the Company with the success of the pre-clinical and clinical studies further validating the effectiveness of CelGro® to enhance the repair of damaged nerves and tendons. Orthocell is well placed to leverage this data and the CE-mark for CelGro® to drive US regulatory applications for Bone, Tendon and Nerve repair."

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

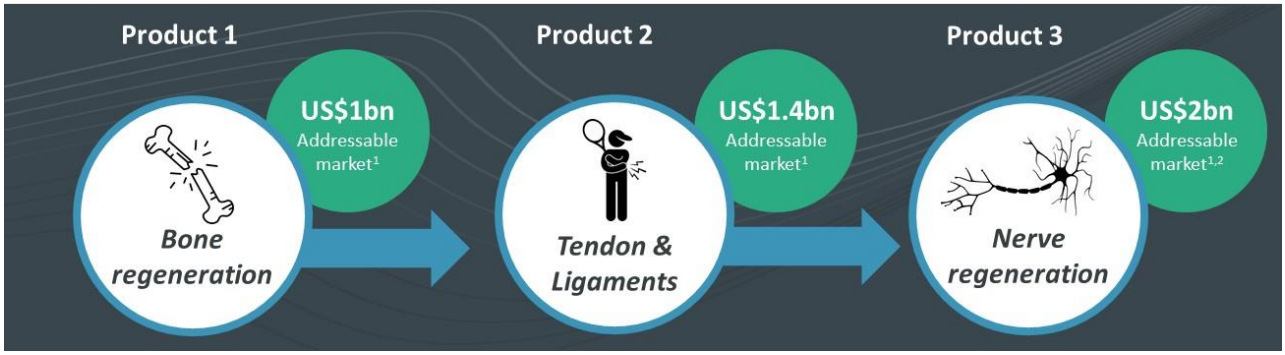
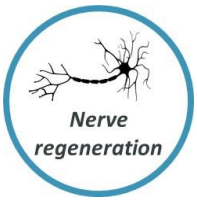


Figure 1: CelGro® Platform Technology



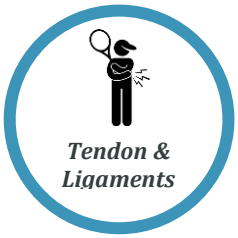
1. CelGro® Nerve Regeneration: "CelGro® pre-clinical study validates high quality nerve repair"

In the previous quarter, Orthocell announced the first four patients successfully completed participation in the CelGro® nerve regeneration clinical trial. Following surgery with CelGro®, patients experienced an 83% improvement in muscle power of affected limbs and had returned to work, sport and normal daily activities. To demonstrate, at a microscopic level, that CelGro® produces a superior quality nerve repair in severed peripheral nerves when compared to the traditional (direct suture) repair method, the Company undertook a pre-clinical animal study. This study was undertaken in rats (not humans), to enable the surgical removal of the repaired nerve for microscopic analysis.

During the quarter, Orthocell announced the results of the pre-clinical study, indicating CelGro® showed superior outcomes in restoration of nerve structure and functional recovery when compared to the traditional direct suturing nerve repair technique. Microscopic analysis showed that CelGro induced a complete regeneration of nerve fibres, restoring them to normal nerve structure. The findings were also supported by early recovery of nerve sensory and muscle functions.
Restoring normal nerve structure is critical for regaining mobility, function and quality of life. These positive results validate the use of CelGro® to guide and support nerve regeneration in severely damaged or severed peripheral nerves of the hand and upper limb.

A short video explaining how CelGro® supports nerve repair can be found here:
https://www.orthocell.com.au/celgro-nerve-1

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



2. **CelGro® Tendon repair: "CelGro® Tendon Regeneration Trial successful final results"**

During the quarter the company announced final results from patients who completed the CelGro® tendon regeneration clinical trial. A review of patients who completed the trial confirmed all patients achieved a successful tendon repair with no revision surgeries reported. The clinical trial and follow-up was conducted in collaboration with leading orthopaedic surgeon, Professor Allan Wang of St John of God Hospital Subiaco and Professor Ming Hao Zheng of the University of Western Australia.

Professor Allan Wang commented, "Rotator cuff tear is very common and repair can be challenging. An effective biological augment to surgical repair is increasingly desired by the orthopaedic community. CelGro® has shown to improve tissue healing and may assist in reducing the surgical revision rate of the rotator cuff tendon."

Patients in the trial had previously suffered full thickness tears of the rotator cuff tendon in the shoulder following work-related, motor vehicle or sporting incidents. Patients experienced chronic pain and difficulty performing basic activities of daily living (i.e. sleeping, bathing and dressing) playing sport and/or working. Previously announced interim clinical results demonstrated that CelGro® was safe, tolerable and capable of guiding tendon healing in the surgical repair of the rotator cuff tendon in the shoulder. Patients reported a return to full range of movement with no pain. 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.

Patient Kevin Winfield said: "My Surgeon told me the tendon in my right shoulder was frayed at the ends and difficult to repair because I'd left it so long. When Dr Wang said that being in the CelGro® study might improve outcomes, I thought it would be worth trying. I'm an active person and wanted long-lasting mobility, without going under the knife again and again. That's why CelGro® made sense for me. So much so, I have gone back to get my other shoulder done too."

A short video explaining how CelGro® strengthens tendon repair can be found here: CelGro®- Next generation tendon repair. CelGro®- Next generation tendon repair

The Company is leveraging this clinical data to complete regulatory submissions for approval of the tendon repair product in the EU, AUS and the US.

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

3. CelGro® Bone and soft tissue repair: "growing international product awareness and expanding regulatory approvals"

Increasing international product awareness

In June 2019, Orthocell announced all patients had successfully completed the CelGro® single-stage dental implant study ("Marketing Study") showing all patients successfully generated enough new bone to stabilise their implants and complete treatment in approximately four months – **almost half the time of the usual two-stage (eight months) dental implant treatment.** The results of this Marketing Study were presented in September 2019 at the 28th Annual European Association for Osseointegration (EAO) scientific meeting in Lisbon and the Annual meeting of the European Centers of Dental Implantology in Dessau. Both meetings were attended by the biggest names in implant dentistry attracting thousands of people from industry and further positioning CelGro® as the best-in-class collagen membrane for dental bone and soft tissue repair.

Growing product use in Centres of Excellence

Orthocell continued to grow the awareness and use of CelGro® in UK based centres of excellence during the quarter. In particular, the Company delivered product presentations to the Harley St Dental clinic consisting of industry leading dentists and oral surgeons delivering world class dental solutions. The team at Harley St are also actively training the new wave of dentists as senior lecturers and members of the royal college of surgeons.

Growing base of brand ambassadors and partner discussions

During the quarter the Company engaged ten (10) industry leading clinicians (KOL's) based in the EU and the US to assist in rolling out the clinician advocacy program, to expand the network of referring clinicians and assist discussions with strategic partners. The Company continues to progress discussions with potential global partners. With EU approval achieved and brand ambassadors appointed to actively represent the product, Orthocell is well placed to execute on its commercial partnering strategy in the near term.

Expanding target market regulatory approvals

In late 2018, Orthocell announced the successful completion of a Pre-Submission Meeting with the US Food and Drug Administration (FDA), to discuss Orthocell's application for regulatory clearance using the 510(k) pathway to get approval to sell CelGro® in the US. The meeting provided an opportunity to discuss the submission and get feedback on the application process. During the quarter, Orthocell continued to progress the regulatory studies required for 510(k) clearance and remains on track to receive FDA approval in 2020.

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

During the quarter Orthocell announced it has submitted an application to the Therapeutic Goods Administration (TGA) for CelGro®'s inclusion on the Australian Registry of Therapeutic Goods (ARTG), a pre-requisite for its introduction into the substantial Australian commercial market. Orthocell's application to the TGA follows its recent approval in Europe (CE Mark) where the Company is gaining significant market traction in key markets including the UK and Italy. With European approval in place, Orthocell is well-positioned to also secure approval in Australia, enabling Orthocell to market and sell CelGro® in dental guided bone and tissue regeneration procedures in 2020.

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.

The company remains on track to complete recruitment for its randomised controlled clinical trial of Ortho-ATI® versus corticosteroid injection by 4Q CY2019.

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.

Corporate

Orthocell was invited to present at the 21st H.C. Wainwright Annual Global Investment Conference held at the Lotte New York Palace Hotel in New York City. Orthocell Managing Director, Paul Anderson will present the latest investor slide deck highlighting the upcoming catalysts. Mr Anderson will also meet with members of the investment community during scheduled one-on-one meetings at the conference.

Orthocell was declared a winner in the national final of the coveted Pitch@Palace competition – a global movement started by the British royal family, which aims to amplify the work of entrepreneurs and deepen their global impact. Orthocell CEO, Paul Anderson, participated in a series of workshops and pitches last week, which culminated in a final three-minute pitch to an audience of more than 200 people at Government House in Perth on Friday tonight. Dignitaries included Duke of York, Prince Andrew, West Australian Governor, Mr Kim Beazley, and former Minister for Foreign Affairs, Julie

[2] US, Japanese, European and Australian markets

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

Bishop, and a range of corporate influencers too. "We expect to gain tremendous exposure via the Pitch@Palace event and the extended alumni community. We are privileged to be a finalist in the global innovation event, showcasing world class innovation at the St James Palace, London in December," said Mr Anderson.

Orthocell's net operating outflows for the quarter were A$1.99m, 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$9.3m. This will allow the Company to continue investing resources to grow the value of its leading regenerative medicine product portfolio, engage strategic partners and progress R&D activities.

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.

For more information, please contact:

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[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	30 September 2019

	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	189	189
1.2	Payments for:		-
	(a) research & development	(803)	(803)
	(b) product manufacture & operating costs	(165)	(165)
	(c) marketing, business development & investor relations	(158)	(158)
	(d) leased assets	(1)	(1)
	(e) staff costs (research & development, production, admin)	(740)	(740)
	(f) administration & corporate costs	(319)	(319)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	12	12
1.5	Interest & other costs of finance paid	(9)	(9)
1.6	Income taxes paid	-	-
1.7	Government grants & tax incentives	-	-
1.8	Other	-	-
1.9	**Net cash from / (used in) operating activities**	**(1,994)**	**(1,994)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) property, plant & equipment	-	-
	(b) businesses (see note 10)	-	-
	(c) investments	-	-
	(d) intellectual property	(62)	(62)
	(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)	(150)
2.6	**Net cash from (used in) investing activities**	**(212)**	**(212)**

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 issue of shares	-	-
3.2	Proceeds from issue of convertible notes	-	-
3.3	Proceeds from exercise of share options	285	285
3.4	Transaction costs related to issues of shares, convertible notes or options	-	-
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**	**285**	**285**

4.	**Net increase / (decrease) in cash & cash equivalents for the period**		
4.1	Cash & cash equivalents at beginning of quarter/year to date	11,236	11,236
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,994)	(1,994)
4.3	Net cash from (used in) investing activities (item 2.6 above)	(212)	(212)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	285	285
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash & cash equivalents at end of quarter**	**9,315**	**9,315**

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	3,315	3,236
5.2	Term deposits	6,000	8,000
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)**	**9,315**	**11,236**

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	
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	530
9.2	Product manufacturing & operating costs	35
9.3	Marketing, business development & investor relations	304
9.4	Leased assets	3
9.5	Staff costs (research & development, production, administration)	931
9.6	Administration and corporate costs	250
9.7	Other (provide details if material)	
9.8	**Total estimated cash outflows**	**2,053**

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: ..... Date: 31 October 2019

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.