Quarterly Report – June 2019

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

Key highlights for the quarter:

- **CelGro® successfully guides and supports nerve regeneration** in severely damaged peripheral nerves of the hand and upper limb. Further clinical update expected Q3 CY 2019.
- **CelGro® halves the time of the usual two-stage (eight months) dental implant treatment**
- **Company advances CelGro® regulatory program** with submission to the TGA (Australia) and progresses market entry study for the FDA (US) submission
- **Orthocell successfully completes $10.6m placement,** with demand for the placement well in excess of funds sought, and supported by existing shareholders, new institutions and other sophisticated investors
- **Year to date total product revenues for the 12 months to 30 June 2019 up 53%** compared to the 12 months to 30 June 2018

Orthocell Managing Director Paul Anderson said: "It has been a very important period for the Company with the success of the capital raise providing an endorsement of Orthocell's business strategy, progress in commercialising CelGro® and the exciting outlook for the Company as it drives it's leading products into key markets. Orthocell is well placed to execute on its partnering strategy, leveraging the CE-mark in the US regulatory approval process and introducing other key CelGro® indications to 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 its 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$2.6bn[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

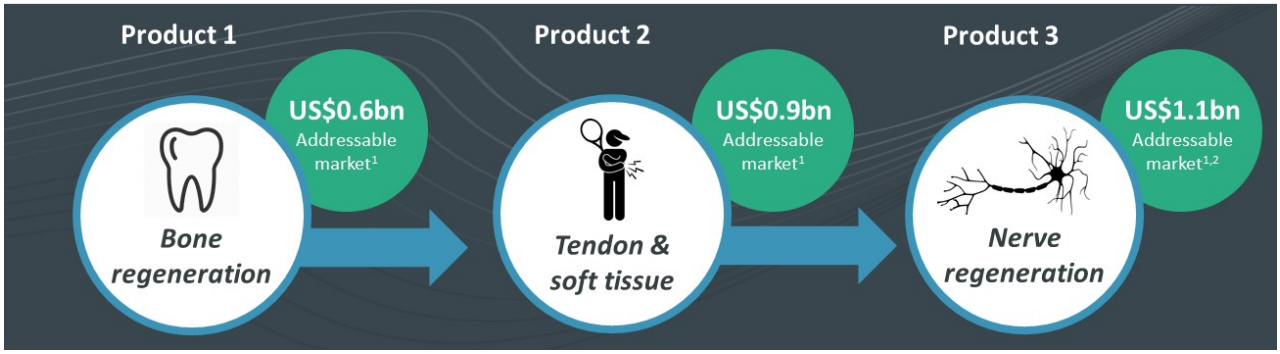
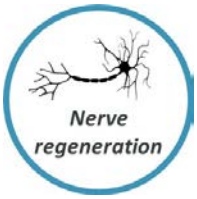


Figure 1: CelGro® Platform Technology



1. CelGro® Nerve Regeneration: "First patients complete nerve regeneration trial"

During the quarter, Orthocell announced clinical results from the first patients to successfully completed participation in the CelGro® nerve regeneration clinical trial. A review of patients 24 months after nerve regeneration treatment with CelGro® (involving the repair of 8 peripheral nerves) indicates that CelGro® successfully guides and supports nerve regeneration in severely damaged peripheral nerves of the hand and upper limb. The patients experienced **83% improvement in muscle power** and have returned to work, sport and activities of daily living after their CelGro® nerve regeneration treatment. A short video explaining how CelGro® supports nerve repair can be found here. https://www.orthocell.com.au/celgro-nerve-1

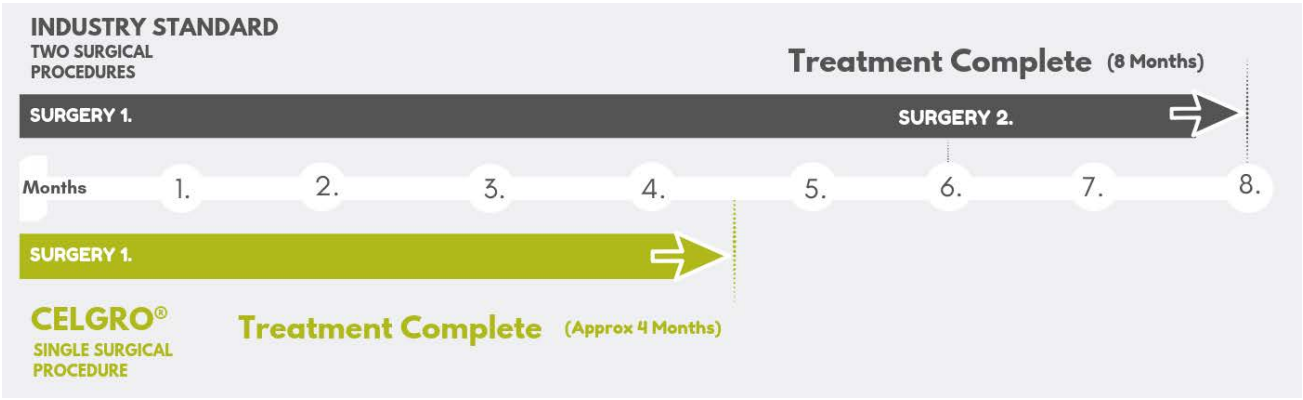
Patient Daniel Hunt, said: After my football injury, I had no feeling in my right shoulder. I couldn't pick up my kids, swim, or play football. When Dr O'Beirne said that being in the CelGro® study might improve outcomes, I thought it would be worth trying. I'm living a normal life now. I can pick up my kids and I even swam a duo to Rottnest! I might even be able to play footy again next year - something that I thought would never happen.

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. Patient treatment is 75% complete with a further clinical update planned for 3Q CY2019.

2. CelGro® Bone and soft tissue repair: "accelerating dental implant treatments, growing international product awareness and expanding regulatory approvals"

Accelerating dental implant treatments

Orthocell announced all patients have successfully completed the CelGro® single-stage dental implant study ("Marketing Study") designed to assess effectiveness and predictability in accelerating dental implant treatment timeframes. Implant surgery with CelGro® had a significant impact on patients' lives. 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 diagram below compares the single stage and two stage surgical dental implant procedures.



Patient Peta Nancarrow said: "My dental implant procedure was a great success. Prior to treatment I couldn't chew properly and was suffering from an inability to eat certain foods. Dr Allan suggested I participate in the CelGro® study as it might improve and accelerate treatment. I'm so glad I did. I have regained the ability to chew all types of food and I am back enjoying a normal diet. I also avoided a second surgical procedure."

Orthocell intends to leverage these supplementary marketing study data to further position CelGro® as the best-in-class collagen membrane for dental bone and soft tissue repair and comes at a time when the Company is active in partnering discussions. The Company is leveraging the EU regulatory approval and finalising its submission for US regulatory clearance (510K).

Global product awareness increasing

During the quarter the Company continued to roll out its KOL-lead clinician advocacy program to expand the network of referring clinicians and assist discussions with strategic partners.

Orthocell completed a European ("EU") tour with Dr Brent Allan (Orthocell's principle investigator and leading Australian maxillofacial surgeon). Dr Allan presented the single-stage dental implant study data to leading dental clinicians and surgeons in Italy, Spain and the UK. Dr Allan highlighted CelGro®'s rapid and superior quality bone regeneration and handling qualities that enabled patients to successfully generate 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.

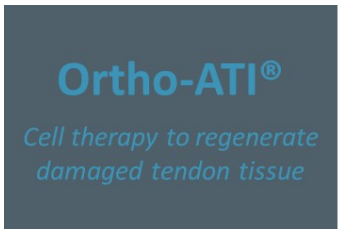
In addition, following the biennial International Dental Show (IDS) held in Cologne, Germany (12-16 March), the Company has shortlisted key clinicians to assist in growing awareness of the product and expects to engage key EU and US based clinics in Q3 CY2019.

The Company continues to progress discussions with potential global partners. With EU approval achieved and brand ambassadors appointed actively representing 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.

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 3Q 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 completed a placement of 26,500,000 ordinary shares at $0.40 per share to raise $10.6 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. The funds raised, in combination with cash reserves, will be used to accelerate commercialisation of CelGro® for dental bone, tendon and nerve repair into key markets; progress key regulatory approvals in the US and other target jurisdictions; and support continued business development and marketing initiatives.

Orthocell's net operating outflows for the quarter were A$1.9m, 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$11.2m. 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 marketing and sales strategy for CelGro® in dental bone and soft tissue repair. This includes engagement of country specific distributors in the EU and undertaking targeted education, promotion and advertising programs 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:

For more information, please contact:

[2] US, Japanese, European and Australian markets

ortho·cell
advancing tissue repair & regeneration

General & Investor enquiries

Paul Anderson
Orthocell Limited
Managing Director
P: +61 8 9360 2888
E: paulanderson@orthocell.com.au

Media enquiries

Haley Chartres
Hales[2] Communications

P: +61 423 139 163
E: haley@h-squared.com.au

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 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. The Company's other major product is 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.

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

+Rule 4.7B

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 Jun 2019

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	246	1,001
1.2	Payments for		
	(a) research & development	(709)	(2,292)
	(b) product manufacturing & operating costs	(224)	(733)
	(c) Marketing, business development & investor relations	(101)	(647)
	(d) leased assets	(1)	(3)
	(e) staff costs (research & development, production, administration)	(886)	(3,234)
	(f) administration & corporate costs	(198)	(697)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	4	11
1.5	Interest & other costs of finance paid	(34)	(34)
1.6	Income taxes paid	-	-
1.7	Government grants & tax incentives	-	2,528
1.8	Other	-	-
1.9	**Net cash from / (used in) operating activities**	**(1,903)**	**(4,100)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) property, plant and equipment	(4)	(15)
	(b) businesses (see item 10)	-	-

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
	(c) investments	-	-
	(d) intellectual property	(155)	(434)
	(e) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) property, plant and equipment	-	-
	(b) businesses (see item 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)	-	-
2.6	**Net cash from / (used in) investing activities**	**(159)**	**(449)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of shares	10,600	12,401
3.2	Proceeds from issue of convertible notes	-	-
3.3	Proceeds from exercise of share options	1,140	1,140
3.4	Transaction costs related to issues of shares, convertible notes or options	(530)	(666)
3.5	Proceeds from R&D tax incentive advance payment facility	-	1,153
3.6	Repayment of borrowings	(1,153)	(1,153)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**10,057**	**12,875**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of quarter/year to date	3,241	2,910
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,903)	(4,100)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(159)	(449)

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
4.4	Net cash from / (used in) financing activities (item 3.10 above)	10,057	12,875
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of quarter**	**11,236**	**11,236**

5.	**Reconciliation of cash and 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'000**	**Previous quarter $A'000**
5.1	Bank balances	3,236	3,241
5.2	Term deposits	8,000	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**11,236**	**3,241**

6.	**Payments to directors of the entity and their associates**	**Current quarter $A'000**
6.1	Aggregate amount of payments to these parties included in item 1.2	306
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 and 6.2

Executive remuneration and non-executive director fees and consulting fees

7.	**Payments to related entities of the entity and their associates**	**Current quarter $A'000**
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 and 7.2

8.	**Financing facilities available** *Add notes as necessary for an understanding of the position*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
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 as well.

9.	**Estimated cash outflows for next quarter (excludes cash inflows)**	**$A'000**
9.1	Research & development	862
9.2	Product manufacturing & operating costs	188
9.3	Marketing, business development & investor relations	174
9.4	Leased assets	1
9.5	Staff costs (research & development, production, administration)	850
9.6	Administration and corporate costs	157
9.7	Other (provide details if material)	-
9.8	**Total estimated cash outflows**	**2,232**

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 July 2019
(Company secretary)

Print name: Simon Robertson

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.