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Quarterly Report – December 2018

Perth, Australia; 31 January 2019: Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to release its Quarterly Report for the quarter ended 31 December 2018.

Key highlights for the quarter:

- Successfully completes a A$1.8 million Placement with support from existing shareholders, senior management and new institutional and wholesale investors
- Executed EU market entry of CelGro®, with approval for use of CelGro® in the highly regarded Birmingham Dental Hospital
- Year to date total revenue receipts (1H FY 2019) up 65% when compared to 1H FY 2018
- Successfully progressed studies required by the FDA for CelGro® to receive 510(k) clearance in the US. Release of top line results is expected 2Q CY 2019.
- Successfully completed treatment of last patient in Orthocell's single-stage dental implant study. Release of top line results is expected in 2Q CY2019.
- Breakthrough bone repair study using CelGro® dosed with bone growth factors presented at European Orthopaedic Research Society meeting validating versatility and potential to extend Orthocell's orthopaedic product range
- Continued progress in pivotal Ortho-ATI® study for chronic tendon repair.

Orthocell Managing Director Paul Anderson said: "We are delighted by the uptake of CelGro®, for dental bone and soft tissue repair applications, with the achievement of first approval in a top tier UK public teaching dental hospital during the quarter. This accelerated uptake combined with overwhelmingly positive user feedback underpins our confidence in gaining significant market traction. Orthocell remains focused on executing its strategic market entry plans into Europe over the next 12 months and is well positioned to build upon the key commercialisation milestones already achieved."

CelGro®: EU market entry for bone and soft tissue repair "CelGro® approved in key UK public dental hospital"

Orthocell has a structured marketing strategy in place and is well positioned to drive product adoption and sales of CelGro® in Europe, following the recent appointments of key opinion leaders in the Dental market to the Medical Scientific Advisory Board, engagement of first distributors and achievement of first product use and sales in Europe.

CelGro® represents a breakthrough in soft tissue reconstruction and offers significant commercial potential in its existing addressable markets of bone, tendon, nerve and cartilage, as well as wider

applications in general surgical and soft tissue reconstructive applications. The global addressable market for CelGro® is in excess of US$2.6bn[1] and growing.

During the quarter, the Company secured approval for use of CelGro® in the highly regarded Birmingham Dental Hospital ("BDH"), one of only ten teaching public dental hospitals in England. The approval for the use of CelGro® at BDH was driven Key Opinion Leader ("KOL") product feedback and recommendation, underpinned by clinical data demonstrating CelGro® assists clinicians in delivering superior tissue repair outcomes (up to 26% better quality newly formed bone) compared to the market leading dental product. This represents the first step in growing Orthocell's public hospital customer base, as part of its commercialisation strategy in Europe and is expected to provide a boost to revenues and accelerate product awareness of CelGro®.

Orthocell also continued to execute targeted education programs and promotion activities to expand product awareness and establish a network of referring periodontists and oral and maxillofacial surgeons. In October 2018, Orthocell presented its successful CelGro® bone repair study results at the 27th European Association for Osseointegration (EAO) Annual Scientific Meeting attended by more than 2,900 delegates. This study demonstrated CelGro® results in up to 26% better quality newly formed bone when compared to market leading comparative product. The EAO Annual Scientific Meeting provided an opportunity to build awareness of the potential patient benefits provided by best in class products such as CelGro®. Orthocell is well positioned to establish CelGro® as the best class membrane for bone repair in the significant and growing global market.

CelGro®: US Regulatory progress and patent protection

In late 2018, Orthocell announced the successful completion of a Pre-Submission Meeting with the United States Food and Drug Administration (FDA), to discuss the submission to gain FDA clearance, enabling the use and sale of CelGro® in the US. The meeting provided an opportunity to discuss progress of submission for CelGro® to receive 510(k) clearance in bone and soft tissue repair in the US. During the quarter, Orthocell continued to progress the regulatory studies required for 510(k) clearance and remains on track to receive FDA approval. Release of top line results is expected 2Q CY 2019.

During the quarter, the Company was granted divisional patents in Japan, Hong Kong and Mexico for its CelGro® collagen medical device platform. The patents cover the method of manufacture of novel bio-scaffolds and method of combining cells and scaffolds as an aid in the surgical repair of soft tissue injuries and protects the CelGro® product platform. CelGro® patents have been previously granted in the US, Europe, China, Canada, Singapore, Australia and New Zealand.

[1] US, Japanese, European and Australian markets

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CelGro®: studies validate versatility and highlight potential to extend the product range in bone repair

During the quarter, Orthocell made significant dental bone and soft tissue clinical development progress successfully completing treatment of the last patient in the single-stage dental implant study. This study is designed to further validate the versatility of CelGro® for dental bone and soft tissue repair and represents a key milestone in Orthocell's marketing strategy, to generate further data and educate surgeons on the benefits of using CelGro. Release of top line results is expected in 2Q CY2019.

The Company also announced a breakthrough bone repair pre-clinical study using CelGro® dosed with bone growth factors presented at European Orthopaedic Research Society meeting in Ireland. This study indicated CelGro® when dosed with bone active factors can accelerate and augment the repair of fractures with cortical bone defects. Accelerated repair of critical bone defects represents an area of significant clinical interest to the orthopaedic community. This study also further validates the versatility of CelGro® and the potential to extend Orthocell's orthopaedic product range.

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

Orthocell continues to enroll patients for its lead clinical trial of Ortho-ATI®. 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.

Ortho-ATI® is a world leading breakthrough in regenerative medicine – a novel, cell therapy developed to treat chronic degenerative tendon injuries (tendinopathy / tendonitis), it can be utilised in both surgical and non-surgical applications. Ortho-ATI® is at the forefront of a large and growing market opportunity where the addressable market is estimated to be >US$7.7bn[2] and growing.

Corporate

During the Quarter Orthocell successfully completed a A$1.8m placement ("Placement"). The Placement was supported by existing shareholders, senior management and new institutional and wholesale investors. The Company also announced a A$2,528,159 Research and Development (R&D) Tax Incentive refund for the financial year 2017/2018. The funds raised, R&D tax refund and growing revenues, in combination with cash reserves, will be used to accelerate market entry of CelGro® for dental bone and soft tissue repair into European markets; progress key regulatory approvals in the US and other target jurisdictions; and support continued business development and marketing initiatives.

[2] US, Japanese, European and Australian markets

Orthocell's net operating outflows for the quarter were A$1.19m, 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$3.5m. 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 strategic market entry plans into Europe for dental bone and soft tissue repair. This incorporates the implementation of product distribution channels, led by its key opinion leaders, designed to optimise shareholder value. These potential product distribution channels include direct ordering mechanisms and external distributor arrangements in key European target markets. Over the medium to long term, Orthocell intends to leverage the CE Mark to accelerate the introduction of the tendon and soft tissue indications and achieve US regulatory approvals, in parallel to the commercialisation of Ortho-ATI® and pipeline products.

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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 TGA-licensed cell therapies Autologous Tenocyte Implantation (Ortho-ATI®) and Autologous Chondrocyte Implantation (Ortho-ACI®), which aim to regenerate damaged tendon and cartilage tissue. 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.

For more information on Orthocell, please visit www.orthocell.com.au or follow us on Twitter **@Orthocelltd** 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	31 December 2018

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	211	443
1.2	Payments for		
	(a) research & development	(634)	(1,092)
	(b) product manufacturing & operating costs	(92)	(308)
	(c) Marketing, business development & investor relations	(292)	(499)
	(d) leased assets	(1)	(1)
	(e) staff costs (research & development, production, administration)	(773)	(1,576)
	(f) administration & corporate costs	(145)	(433)
1.3	Dividends received (see note 3)		
1.4	Interest received	3	5
1.5	Interest & other costs of finance paid		
1.6	Income taxes paid		
1.7	Government grants & tax incentives	528	2,528
1.8	Other		
1.9	**Net cash from / (used in) operating activities**	**(1,194)**	**(932)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) property, plant and equipment	(5)	(10)
	(b) businesses (see item 10)	-	-

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
	(c) investments	-	-
	(d) intellectual property	(22)	(138)
	(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**	**(27)**	**(148)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of shares	1,801	1,801
3.2	Proceeds from issue of convertible notes	-	-
3.3	Proceeds from exercise of share options	-	-
3.4	Transaction costs related to issues of shares, convertible notes or options	(128)	(128)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
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**	**1,673**	**1,673**

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	3,052	2,910
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,194)	(932)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(27)	(148)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1,673	1,673

Consolidated statement of cash flows		**Current quarter** **$A'000**	**Year to date (6 months)** **$A'000**
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of quarter**	**3,503**	**3,503**

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		
5.2	Call deposits	-	-
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)**		

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	217
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**	**$A'000**
9.1	Research & development	375
9.2	Product manufacturing & operating costs	62
9.3	Marketing, business development & investor relations	45
9.4	Leased assets	1
9.5	Staff costs (research & development, production, administration)	578
9.6	Administration and corporate costs	230
9.7	Other (provide details if material)	-
9.8	**Total estimated cash outflows**	**1,291**

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 L Robertson.

..... Date: 31 January 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.