

Quarterly Report – June 2018

Perth, Australia; 31 July 2018: Orthocell Limited (ASX:OCC, “Orthocell” or the “Company”) is pleased to release its Quarterly Report for the quarter ended 30 June 2018.

Key highlights for the quarter:

- Executed EU market entry of CelGro[®], with the appointment of exclusive distributors
- Achieved first product use and sales of CelGro[®] within ~6 months of receiving CE Mark for dental bone and soft tissue repair
- Achieved positive clinical data results in CelGro[®] across dental and tendon indications
- Announced positive Ortho-ATI[®] results for treatment of tennis elbow
- Appointed Dr Jonathan Bell to the MSAB to support and accelerate orthopaedic development

Orthocell Managing Director Paul Anderson said: “We are delighted by the rapid uptake of CelGro[®], for dental bone and soft tissue repair applications, with the achievement of first product use and sales shortly after receiving the CE Mark in late 2017. 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 in the next financial year, and is well positioned to build upon the key commercialisation milestones already achieved.”

CelGro[®]: EU market entry and clinical development for bone and soft tissue repair

During the quarter, the Company appointed Bimar Ortho (“Bimar”) and Komak Sp (“Komak”) as exclusive distributors for its innovative medical device CelGro[®] for dental bone and soft tissue repair in Italy and Poland respectively. Both Bimar and Komak are leading distributors with established networks and have a proven track record in driving market entry of high quality products. Both distributors will work collaboratively with the Company to execute targeted promotion activities, expand product sales and develop the network of product users. Subsequent to the quarter, Orthocell appointed Carrera Medical as its exclusive UK distributor of CelGro[®] for dental bone and soft tissue repair on 10 July 2018.

The appointment of exclusive distributors underpinned Orthocell’s achievement of first product use and sales in Europe for dental bone and soft tissue. This significant milestone was achieved across multiple European regions: UK and Poland during the quarter; Italy and Ireland subsequent to the quarter.

In addition to market entry activities, the Company announced the completion of a clinical study using CelGro[®] for treatment of dental bone defects on 1 May 2018. The study results demonstrated that CelGro[®] guides superior quality bone formation when used to treat bone defects and CelGro[®]



resulted in up to 26% better quality newly formed bone when compared to market leading comparative product. The study was performed in collaboration with leading West Australian maxillofacial surgeon Dr Brent Allan, Professor Ming Hao Zheng from the University of Western Australia and St John of God Hospital Subiaco.

During the quarter the Company announced that it has been granted a European patent for its CelGro® collagen medical device platform for soft tissue regeneration and repair applications. This patent covers the method of manufacture of novel bio-scaffolds to aid in the surgical repair of soft tissue injuries and is an addition to the suite of CelGro® patents now granted in the US, China, Canada, Singapore, Australia and New Zealand. The patent entitled “Method for Producing a Collagen Membrane and Uses Thereof” provides additional important intellectual property to protect the CelGro® product platform.

CelGro®: significant progress in clinical development for tendon and soft tissue repair

Orthocell made significant clinical development progress during the quarter. On 6 June 2018, the Company announced new successful study results demonstrating CelGro® is safe, tolerable and capable of guiding tendon healing in the surgical repair of the rotator cuff tendon within the shoulder. Patients experienced, at 6 and 12 months post-treatment, a reduction in pain and an improvement in function and quality of life and no tendon re-tears were reported following surgical repair with CelGro®. The study results were presented at the 2018 APKASS Congress in Sydney, Australia. The study is being performed in collaboration with Clinical Professor Allan Wang (a leading Australian orthopaedic specialist), Professor Ming Hao Zheng (from the University of Western Australia) and St John of God Subiaco Hospital and designed to evaluate the performance of CelGro® collagen medical device for tendon regeneration.

On 25 June 2018, Orthocell appointed globally recognised UK orthopaedic surgeon, Dr Jonathan Bell, to the Medical and Scientific Advisory Board (MSAB). This strategic appointment underpins Orthocell’s key opinion led commercialisation strategy of CelGro® platform technology in key market and supports the medium term strategy to accelerate orthopaedic development.

Ortho-ATI®: for tendon repair

In June 2018, the Company announced updated positive results from a study of Ortho-ATI® for tennis elbow in patients who suffered work related injuries. The study results demonstrated that patients who had failed other existing treatments for tennis elbow, were able to return to work after Ortho-ATI® treatment, with 88% of patients in the study returning to work. The results were presented at TOBI regenerative medicine meeting in Las Vegas, US and the study was performed in collaboration with Professor Ming Hao Zheng (University of Western Australia) and leading orthopaedic surgeons Dr Jeff Hughes and Dr Alex O’Beirne.



Orthocell continues to enrol 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.

Corporate

Orthocell's net operating outflows for the quarter were A\$1.7m, with the majority of expenditure related to production and R&D activities. At the end of the financial year, Orthocell held a cash balance of A\$2.9m, and expects to receive R&D tax incentive cash refund estimated to be more than A\$2.0m in October 2018.

During the quarter, Cedrus Investments ("Cedrus") initiated research coverage on Orthocell. The Cedrus research report can be viewed here: <https://www.orthocell.com.au/analyst-coverage-1/>

Outlook

Following the receipt of EU market authorisation (CE Mark) for CelGro®, 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.

The achievement of CE Mark validates CelGro®'s manufacturing quality and product performance, in addition to being allowed to be sold within the EU, and provides a strong foundation for expansion into other indications (such as tendon and nerve indications) and regulatory approvals outside the EU. 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 ongoing development and commercialisation of Ortho-ATI® and pipeline products.

For more information, please contact:

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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 [@OrthocellLtd](https://twitter.com/OrthocellLtd) and LinkedIn www.linkedin.com/company/orthocell-ltd



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

57 118 897 135

Quarter ended ("current quarter")

30 June 2018

Consolidated statement of cash flows		Current quarter	Year to date
		\$A'000	(12 months)
			\$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	166	563
1.2	Payments for		
	(a) research & development	(493)	(2,067)
	(b) product manufacturing & operating costs	(68)	(534)
	(c) Marketing, business development & investor relations	(339)	(1,186)
	(d) leased assets	(1)	(13)
	(e) staff costs (research & development, production, administration)	(758)	(3,037)
	(f) administration & corporate costs	(245)	(751)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	5	18
1.5	Interest & other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants & tax incentives	-	2,363
1.8	Other	-	-
1.9	Net cash from / (used in) operating activities	(1,733)	(4,644)
2.	Cash flows from investing activities		
2.1	Payments to acquire:		
	(a) property, plant and equipment	(1)	(87)
	(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	(42)	(287)
	(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	(43)	(374)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of shares	-	2,958
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	-	(76)
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	-	2,882

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	4,686	5,046
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,733)	(4,644)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(43)	(374)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	2,882

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of quarter	2,910	2,910

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	2,910	4,686
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)	2,910	4,686

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	254
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 <i>Add notes as necessary for an understanding of the position</i>	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	500
9.2 Product manufacturing & operating costs	152
9.3 Marketing, business development & investor relations	157
9.4 Leased assets	1
9.5 Staff costs (research & development, production, administration)	836
9.6 Administration and corporate costs	236
9.7 Other (provide details if material)	-
9.8 Total estimated cash outflows	1,882

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

- This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- This statement gives a true and fair view of the matters disclosed.

Sign here: 

 (Director/Company secretary)

Date: 31 July 2018

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.