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Quarterly Report – March 2020

Perth, Australia - 30 April 2020: Orthocell Limited (ASX:OCC, "Orthocell" or "the Company") is pleased to release its Quarterly Report for the quarter ended 31 March 2020.

Key highlights for the quarter:

- **Completed US FDA regulatory study** demonstrating successful bone growth using CelGro®. US regulatory application in final stages of completion;
- **Approval to commence CelGro® nerve regeneration US regulatory (FDA) animal study** expected shortly;
- **Nearing completion of recruitment to the randomised controlled clinical trial of Ortho-ATI® versus corticosteroid injection** in collaboration with with DePuy Synthes Products, Inc., part of the Johnson & Johnson Medical Device Companies;
- **Publication of successful Rotator Cuff Regeneration case study** focussing on Orthocell's autologous tenocyte implantation (Ortho-ATI®) injection therapy to treat chronic degenerative rotator cuff tendinopathy;
- **Granted new patents for CelGro® platform technology** in Canada and Japan covering the method of manufacture of collagen medical devices and as an aid in the surgical;
- **Received A$2.9m R&D tax incentive refund.**

Orthocell Managing Director Paul Anderson said: "Orthocell has continued to progress key clinical, regulatory and commercial initiatives despite recent limitations on domestic and global business operations to contain the spread of COVID-19. The Company is in a strong cash position of >$20m and well positioned to deliver US and AUS approval/s of CelGro and advance development and commercialisation of Ortho-ATI®."

CelGro®
Soft tissue reconstruction platform medical device

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

[1] US, Japanese, European and Australian markets

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

CelGro® as the best-in-class membrane for bone and soft tissue repair and realise multiple commercial partnering opportunities.

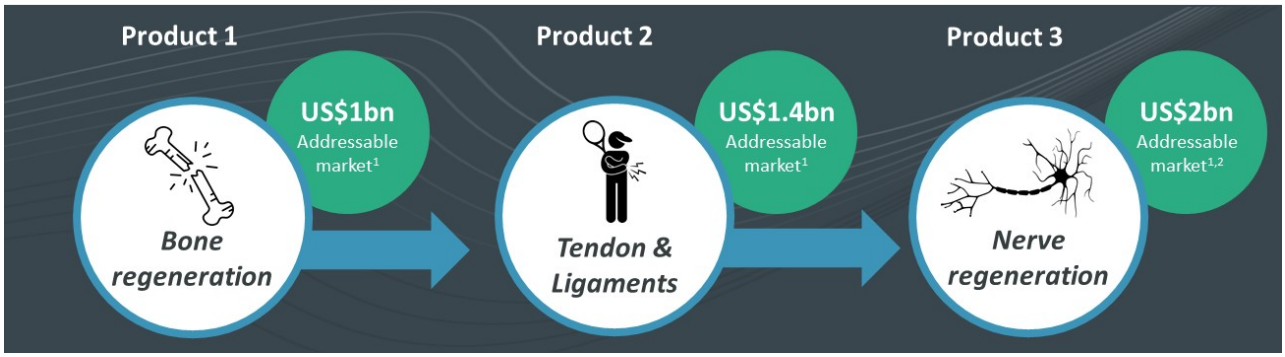


Figure 1: CelGro® Platform Technology

1. CelGro® Bone and soft tissue repair: "Expanding target market regulatory approvals"

During the quarter, Orthocell announced positive results from its guided bone regeneration study, a key component of the FDA submission to gain US marketing approval to supply CelGro® in guided bone regeneration procedures, especially in conjunction with dental implants. The study showed CelGro® is effective in facilitating bone regeneration when used in conjunction with bone substitute and a dental implant, and provides critical regulatory data for the US regulatory submission. The Company was on track to complete the US 510(k) regulatory application by end of Q1 CY2020; however COVID-19 restrictions has impacted this timeline. The Company is now rapidly finalising its submission documents and planning a US 510(k) regulatory application shortly.

Increasing product awareness and use in centres of excellence

During the quarter, the Company continued its clinician advocacy program to expand the network of referring clinicians and product use in centres of excellence. Orthocell sponsored six educational workshops undertaken by key opinion leaders (KOL's) within the Association of Dental Implantology in the UK and Spain during the quarter. Four workshops profiling the use of CelGro were held in the UK and two in Spain with topics including "The Implant Occlusal Connection" and "Guided Surgery, From Dental Reconstruction to Facial Reconstruction - The Lesson Learned".

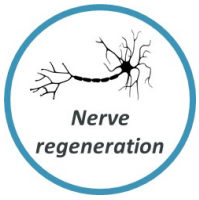
Video conferences were held in place of in person meetings due to COVID-19 restrictions and were effective in maintaining contact and continued development of strategic relationships with industry leading clinicians in the UK, Spain, Germany, Italy and the US.

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

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. An additional 53 units of CelGro® were used via the SAS during the quarter (33 dental, 9 cartilage, 8 tendon and 3 nerve repair cases) increasing the total SAS cases to 175 in Australia to date.

Continuing partner discussions

The Company continues to progress discussions with potential global partners. With EU approval achieved, twelve industry leading KOL's (including five based in the US) appointed, and a US market authorisation submission forthcoming, Orthocell is well placed to execute on its commercial partnering strategy for the Dental indication.

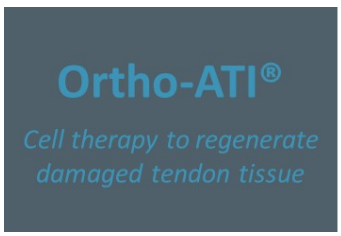


2. CelGro® Nerve Regeneration: CelGro® nerve regeneration trial nearing completion

During the quarter, Orthocell progressed the CelGro® nerve regeneration trial and is in final stages of completing patient recruitment. The Company remains focussed on completing this trial and leveraging the data for regulatory submissions in the US and Australia.

In December 2019, Orthocell received confirmation from the FDA that the proposed CelGro® nerve regeneration animal study protocol meets requirements to support a US 510(k) submission. The company is awaiting final approval from the ethics committee to commence the animal study. Whilst final approval has been delayed due to COVID-19, the Company anticipates it will receive approval to commence shortly.

The Company was on track to complete TGA (AUS) regulatory application by end of Q1 CY2020. Whilst COVID-19 has impacted this timeline, the Company is rapidly finalising its documents and is targeting a submission by 2Q CY2020.



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).

The company is nearing completion of recruitment to the randomised controlled clinical trial (RCT) of Ortho-ATI® versus corticosteroid injection. Due to the complexity of conducting a RCT, Orthocell has experienced some delays in recruitment; but it is not reflective of the significant patient population that is applicable for treatment with Ortho-ATI®.

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

This is a complex and highly focused RCT, directed by the sponsor, to provide clear safety and effectiveness outcomes ("outcome measures") regarding Ortho-ATI® compared to corticosteroid injection in the treatment of rotator cuff tendinopathy and tear. To provide clear and unpolluted outcome measures, the inclusion and exclusion criteria is very defined and consistent with best practice. Patients are excluded from the RCT if they present with any of the 16 exclusion criteria, including, but not limited to, previous treatment injections in the prior three months, previous shoulder surgery or significant pathology of affected shoulder (e.g. inflammatory joint disease) or bilateral shoulder pathology. Whilst this excludes the majority of patients from participating in the study, normally applicable for treatment with Ortho-ATI®, it ensures the outcome measures of the RCT are not masked by prior treatments or other medical conditions.

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 RCT 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.

US FDA Regenerative Medicine Advanced Therapy Designation

The Company has continued working on submission documents required to support a Regenerative Medicine Advanced Therapy application ("RMAT") to the US FDA. RMAT designation provides increased meeting opportunities with FDA and ongoing guidance and support with regards to market entry applications and approvals. The Company remains focussed on submitting the RMAT applications and is finalising submission documents.

Successful Rotator Cuff Regeneration Publication

Orthocell announced the publication of a successful case study focusing on Ortho-ATI® therapy to treat chronic degenerative rotator cuff tendinopathy. The case study was published by leading sports and exercise physicians A/Professor Jane Fitzpatrick, Dr Bonnie McRae and Dr Hussain Khan.

This case report was designed to assess the role and effectiveness of Ortho-ATI® as a minimally invasive cellular injection therapy to treat chronic degenerative rotator cuff tendinopathy in a 77 year-old male. The patient suffered from chronic left shoulder pain for over three years affecting his ability to work, play sport and frequently kept him awake at night. The patient underwent numerous conservative treatment options including physiotherapy, injection therapy (prolotherapy) without success. The patient's condition was confirmed by MRI of the shoulder which noted significant pathology, including severe supraspinatus tendinosis.

Pain and function improvement, including a return to gardening, was reported by the patient at the six-week post-implantation review. At eight months post treatment, and a physiotherapy led

[2] US, Japanese, European and Australian markets

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

strength-based exercise program, the patient reported a return to sleeping normally, gardening and golf without pain. At 12 months, the patient was completely symptom free, had a complete range of movement and was even able to do 30 push-ups every day without concern. A structural improvement in the tendon was confirmed by repeat MRI.

The case report further supports Ortho-ATI® as a durable, long term solution for degenerate, treatment resistant tendons. The case report may be viewed here: Rotator Cuff Regeneration Publication.

Corporate

During the quarter the Company had net operating cash inflows of approximately A$1,000,000. In January the Company received a Research and Development (R&D) Tax Incentive refund of A$2,904,545 for the financial year 2018/2019. The majority of operating expenditure was related to R&D related activities totaling approximately A$1,500,000. At the end of the quarter, Orthocell held a cash balance of A$21.7m.

Orthocell's strong cash position enables the Company to progress regulatory approvals, establish commercial infrastructure and execute on its partnering strategy, delivering significant shareholder value.

As detailed in Section 6.1 of Appendix 4C, payments to related parties include salaries, fees and superannuation contributions.

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 drive the introduction of the nerve and tendon indications, in parallel to the commercialisation of Ortho-ATI® and pipeline products.

[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 orthopedic, 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

Name of entity

Orthocell limited

ABN	**Quarter ended ("current quarter")**
57 118 897 135	31 March 2020

Consolidated statement of cash flows		**Current quarter $A'000s**	**Year to date (9 months) $A'000s**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	118	467
1.2	Payments for:		
	(a) research & development (including allocated staff costs)	(1,534)	(4,956)
	(b) patent fees	(21)	(220)
	(c) marketing, business development & investor relations	(179)	(601)
	(d) leased assets	(1)	(2)
	(e) staff costs (other than R&D staff)	(154)	(455)
	(f) administration & corporate costs	(174)	(503)
1.3	Dividends received (see note 3)		
1.4	Interest received	36	71
1.5	Interest & other costs of finance paid		(10)
1.6	Income taxes paid		
1.7	Government grants & tax incentives	2,905	2,905
1.8	Other		
1.9	**Net cash from / (used in) operating activities**	**996**	**(3,304)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant & equipment	(28)	(29)
	(d) investments	-	-
	(e) intellectual property	(120)	(394)
	(f) other non-current assets		
	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant & equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) 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)	-	(300)
2.6	**Net cash from (used in) investing activities**	**(148)**	**(723)**

Consolidated statement of cash flows	**Current quarter $A'000s**	**Year to date (9 months) $A'000s**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	14,423
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of share options	86	754
3.4	Transaction costs related to issues of equity securities, or convertible notes	(10)	(660)
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**	**76**	**14,517**

4.	**Net increase / (decrease) in cash & cash equivalents for the period**		
4.1	Cash & cash equivalents at beginning of period	20,802	11,236
4.2	Net cash from / (used in) operating activities (item 1.9 above)	996	(3,304)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(148)	(723)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	76	14,517
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash & cash equivalents at end of period**	**21,726**	**21,726**

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	4,726	16,802
5.2	Term deposits	17,000	4,000
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)**	**21,726**	**20,802**

6.	**Payments to related parties of the entity & their associates**	**Current quarter $A'000s**
6.1	Aggregate amount of payments to these parties included in item 1	215
6.2	Aggregate amount of payments to these parties included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

7	**Financing facilities available** *Note: the term 'facilty' includes all forms of financing arrangements available to the entity. 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**
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	-	-

7.5	**Unused financing facilites available at quarter end**	-

7.6 Include in the box 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 a note providing details of those facilities as well.

8.	Estimated cash available for future operating activities	$A'000s
8.1	Net cash from / (used in) operating activities (item 1.9) excluding funds received from government grants & tax incentives (item 1.7)	(1,909)
8.2	Cash and cash equivalents at quarter end (item 4.6)	21,726
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	21,726
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**11**

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

1. Does the entity expect that it will continue to have the current level of net operating cash flows for the time being

Answer:

2. Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful.

Answer:

3. Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer:

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.

Date: 30 April 2020

Authorised by: Simon Robertson
(Name of body or officer authorising release - see note 4)

Notes

1 This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2 If this quarterly cash flow 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 cash flow 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.

4 If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5 If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's Corporate Governance Principles and Recommendations, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.