ortho·cell
advancing tissue repair & regeneration

Quarterly Report – June 2020

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

Key highlights for the quarter:

- **Submission of US FDA regulatory application for CelGro®** for dental guided bone and soft tissue regeneration applications
- **Appointment of experienced medical technology (medtech) executive, Leslie Wise, JD, as Executive Director**
- **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;
- **Announcement of the results from 2019 Annual Quality Study ("AQS"), showing an 87.5% patient satisfaction rating using Ortho-ATI® cell therapy** for the treatment of chronic tendon injuries of the shoulder and a 74.3% patient satisfaction rating for all indications combined.

Orthocell Managing Director Paul Anderson said: "Orthocell is progressing towards regulatory approvals for CelGro in the major global jurisdictions and is well on the way to having a formidable portfolio of CelGro products within the bone tendon and nerve space. This is a unique position internationally and sets a perfect platform for us to continue to grow the value of as individual product segments but importantly grow the value of the company."

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. 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 to 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

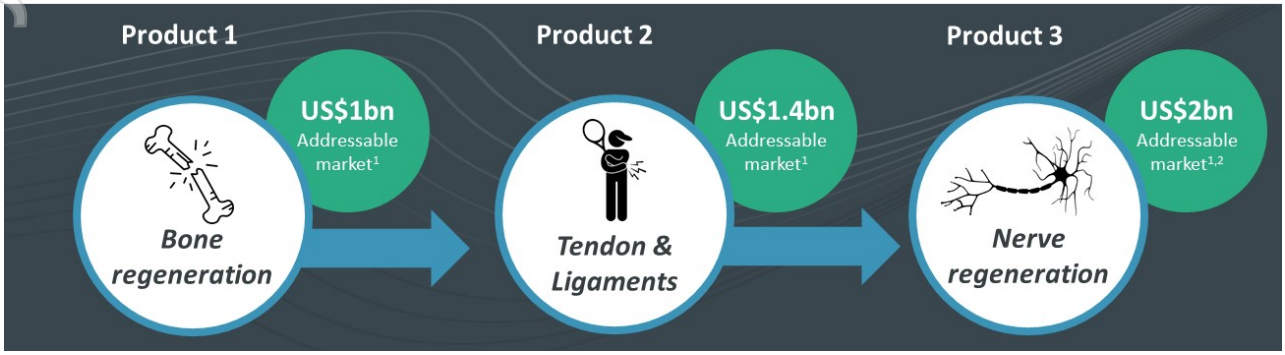


Figure 1: CelGro® Platform Technology

1. CelGro® Bone and soft tissue repair

The Company remains committed to engaging strategic partners to manage the distribution and marketing of CelGro® for dental bone and soft tissue repair procedures. With scalable manufacturing in place, EU regulatory approval, AUS and US submissions in progress, and industry leading brand ambassadors using the product, Orthocell is well positioned to execute on its partnering strategy and to generate revenue.

Expanding target market regulatory approvals

During the quarter, Orthocell announced submission to the US Food and Drug Administration (FDA) seeking 510(k) clearance for marketing its CelGro® product for dental guided bone and soft tissue regeneration applications. The US 510(k) submission follows positive results from its US regulatory study showing CelGro® is effective in facilitating bone regeneration when used in conjunction with bone substitute and a dental implant. The US FDA provides 90-180 days of their resources and time to evaluate each submission. Orthocell is working towards US 510(k) clearance by 2Q CY2021 to allow time for interactions with the FDA regarding the submission.

The US 510(k) submission compliments Orthocell's current "in progress" regulatory submission to the Therapeutic Goods Administration ("TGA") in Australia for approval to market CelGro® for dental bone and soft tissue regeneration applications. The Company held progress discussions with the TGA regarding its submission during the quarter and remains on track for Australian market approval in CY 2020. The Company is now finalising plans for introduction to the Australian market and to grow product awareness and use in key accounts.

Increasing product awareness and use in centres of excellence

The Company has confirmed that dental surgeon's commenced return to work in the EU and the UK in mid to late June, following a period of COVID-19 restrictions which prevented dental procedures. During the quarter the Company continued its clinician advocacy program to grow product awareness and to use in centres of excellence through the delivery and sponsorship of dental implant

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

and guided bone regeneration webinars, in place of in person workshops and symposia attendance. In particular, the Company sponsored a dental industry webinar, attended by 2,100 physicians and industry personnel in the EU/UK on "The New Normal - Dental Response to COVID-19". The Company also presented at The City of London Dental School webinar on "Osteoconductive Collagen Membrane for Guided Bone Regeneration".

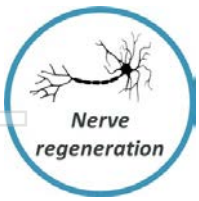
The Company is in the final stages of recruiting an experienced in-country (EU/UK) dental product distribution management expert to improve the representation of the product, engage higher quality distributors, and assist servicing key opinion leaders to grow product use of CelGro® in dental guided bone regeneration procedures.

The Company continues to supply 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 44 units of CelGro® were used via the SAS during the quarter (27 dental, 5 cartilage, 11 tendon and 1 nerve repair cases) increasing the total SAS cases to 219 in Australia to date.

Industry leading brand ambassadors

The Company's US based brand ambassadors were each sent a CelGro® welcome pack during the quarter, containing product summary's, IFU's, marketing material and a product sample to further familiarise them with the product and our marketing collateral.

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 and Italy.



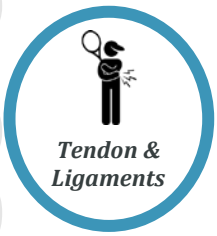
2. CelGro® Nerve Regeneration: CelGro® nerve regeneration trial nearing completion and expanding target market regulatory approvals

During the quarter, Orthocell progressed the CelGro® nerve regeneration trial with one patient remaining to complete recruitment to the 30 patient trial. The Company remains focused on completing this trial and leveraging the data for commercialisation in AUS and the US.

Commencement of the US regulatory study to support a US 510(k) submission for clearance to market CelGro® for peripheral nerve regeneration applications was delayed during the quarter due to COVID-19 restrictions. The Company has been advised during the quarter that restrictions on undertaking research have been lifted at the University of Western Sydney, where the Company is conducting the US regulatory study, and that surgical procedures can commence in early September. The Company will notify the ASX when surgical procedures commence.

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

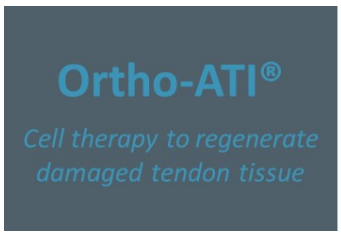
On the 30th July, the Company submitted an application to the TGA for approval to market CelGro® for peripheral nerve regeneration applications in Australia. This was a very important milestone for the Company as it continues to commercialise the CelGro® collagen medical device platform and prepare for entry to strategic markets.



3. CelGro® Tendon and Ligament Regeneration

The Company has progressed implementation of its regulatory strategy to achieve US and AUS approval to market CelGro® for tendon repair procedures. The Company is continuing to work on the US study design and to prepare for a US FDA pre-submission meeting.

With the application to the TGA for approval to market the CelGro® product for peripheral nerve regeneration applications in Australia submitted, the regulatory and research team is now focused on the TGA submission for approval to market the CelGro® product for tendon repair procedures and is on track for a submission in Q4 CY 2020.



Ortho-ATI®: progressing Johnson & Johnson collaboration

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.

During the quarter the Company announced that recruitment to the Ortho-ATI® shoulder tendon study in collaboration with DePuy Synthes Products, part of the Johnson & Johnson Medical Devices Companies ("Sponsor"), is completed. Post the end of the quarter, the Company held a progress meeting with the Sponsor covering matters relevant to the status of the trial and remains focused on completing the trial and providing study outcomes to the Sponsor.

US FDA clinical development plan and regulatory pathway

During the quarter, the Company engaged Greenleaf Health ("Greenleaf"), a US based specialist regulatory consulting firm with particular expertise in cell and gene therapy product development and US FDA regulatory submissions and interactions. Greenleaf were engaged to review the Company's clinical development plan and the draft US study protocol required to progress commercialisation in the US and assess the applicability of Ortho-ATI® for FDA expedited programs and priority review designations. Whilst the engagement of Greenleaf has delayed submission of the

[2] US, Japanese, European and Australian markets

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

Investigation New Drug ("IND") and Regenerative Medicine Advanced Therapy ("RMAT") application, it will ensure the IND submission is tailored to the current regulatory guidelines and positions the Company to leverage the strategic benefits provided by applicable expedited programs and priority review designations.

RMAT designation provides increased meeting opportunities with the FDA and ongoing guidance and support with regards to market entry applications and approvals. The Company remains focused on submitting the RMAT applications and is finalising submission documents.

Successful Annual Quality Survey

As part of Orthocell's commitment to its continuous delivery of high quality regenerative medicine products, the Company administers an Annual Quality Study ("AQS") to capture patient feedback following treatment of chronic tendon injuries with Orthocell's Ortho-ATI® cellular therapy.

On the 9th July, the Company announced the results from its 2019 AQS and trends since 2015. Summary results included:

- 87.5% satisfaction in patients who received Ortho-ATI® tendon repair treatment, in the shoulder, in the four AQS surveys conducted between 2015 and 2019
- 74.2% satisfaction in patients who received Ortho-ATI® tendon repair treatment in the four AQS surveys conducted between 2015 and 2019
- 2019 AQS included treatment of six (6) different anatomical locations (tendons) including Elbow (56%), Shoulder (18%), Hip (13%), Knee (3%) Achilles/ankle/foot (10%)

Corporate

Orthocell appointed Leslie Wise to the Board of Directors during the quarter. Leslie has extensive experience in securing US market access and reimbursement for medical devices as well as serving in various senior management positions across large US medical device and pharmaceutical companies. Leslie's depth of knowledge and expertise is ideally suited to the Company's product range and the next phase of growth for Orthocell.

Orthocell's operating cash flows for the quarter were A$1.25m, 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$20.4m.

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.

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

Release authorised by:
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Managing Director, Orthocell Limited

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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® platform technology, a collagen medical device which facilitates tissue repair and healing in a variety of orthopaedic, reconstructive and surgical applications. Orthocell has received European regulatory approval (CE Mark) for CelGro® and is marketed within the European Union for a range of dental bone and soft tissue regeneration procedures. CelGro® is being readied for first approval in the US and AUS. The Company's other major focus 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

Forward Looking Statement

Any statements in this press release about future expectations, plans and prospects for the Company, the Company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate, "expect," "intend," "may," "plan," "predict," "project," "target, "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to successfully develop its product candidates and timely complete its planned clinical programs and the Company's ability to obtain marketing approvals for is product candidates. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

[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	30 June 2020

	Consolidated statement of cash flows	**Current quarter $A'000s**	**Year to date (12 months) $A'000s**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	232	742
1.2	Payments for:		
	(a) research & development (including allocated staff costs)	(1,113)	(6,045)
	(b) patent & trademark fees	(71)	(416)
	(c) marketing, business development & investor relations	(131)	(695)
	(d) leased assets	(1)	(2)
	(e) staff costs (other than R&D staff)	(144)	(598)
	(f) administration & corporate costs	(67)	(923)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	45	116
1.5	Interest & other costs of finance paid	-	(10)
1.6	Income taxes paid	-	-
1.7	Government grants & tax incentives	-	2,905
1.8	Other	-	
1.9	**Net cash from / (used in) operating activities**	**(1,250)**	**(4,926)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant & equipment	(25)	(32)
	(d) investments	-	-
	(e) intellectual property	(9)	(53)
	(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**	**(34)**	**(385)**

Consolidated statement of cash flows		Current quarter $A'000s	Year to date (12 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	-	754
3.4	Transaction costs related to issues of equity securities, or convertible notes	-	(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**	**-**	**14,517**

4.	**Net increase / (decrease) in cash & cash equivalents for the period**		
4.1	Cash & cash equivalents at beginning of period	21,726	11,236
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,250)	(4,926)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(34)	(385)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	14,517
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash & cash equivalents at end of period**	**20,442**	**20,442**

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	5,442	4,726
5.2	Term deposits	15,000	17,000
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)**	**20,442**	**21,726**

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	123
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)	(1,250)
8.2	Cash and cash equivalents at quarter end (item 4.6)	20,442
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	20,442
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**16**

Note: if the entity has reported positive net operating cash flows in item 1.9 answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5

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: N/A

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: N/A

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: N/A

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: 31-Jul-20

Authorised by: Simon Robertson, Company Secretary
(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.