

## **Quarterly Cash Flow Report – December 2015**

**Perth, Australia; 29 January 2016:** Orthocell Limited's Quarterly Cash Flow Report for the quarter ended 31 December 2015 is attached.

Orthocell is a commercial-stage, regenerative medicine company focused on regenerating mobility for patients and the ageing population by developing products for a variety of tendon, cartilage and soft tissue injuries. Orthocell's portfolio of products include TGA-licensed stem 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 and is being readied for first regulatory approvals.

During the quarter the Company continued to progress the development of its lead products and pipeline opportunities. Orthocell also raised \$4.4 million via a placement to selected institutional investors in the US, Australia and various directors and officers of the Company. The funds raised from the placement will progress the Company's portfolio of products, assist in driving entry to the world's largest markets and for working capital purposes.

The Company was also granted several key patents in Canada covering the combination of bio-scaffolds and tenocytes; in Australia for the method to manufacture Celgro<sup>TM</sup> soft tissue reconstructive, collagen based medical device; and in Hong Kong for the method to manufacture Ortho-ATI<sup>TM</sup> for the regeneration of damaged tendons.

In December Orthocell received approval for a human clinical study examining the safety and effectiveness of its Celgro<sup>TM</sup> SMRT Graft<sup>TM</sup> collagen scaffold, used as an augment to the surgical repair of the rotator cuff tendon in the shoulder. The study will commence in Q1 2016, involve 30 patients in Perth, Western Australia, and will be conducted by some of Australia's leading orthopaedic surgeons.

In November the Company announced initial positive safety and tolerability results for  $Celgro^{TM}$  in a pilot clinical study examining the safety and effectiveness of  $Celgro^{TM}$  for the treatment of bone defects around dental implants.

In October Orthocell announced the release of new positive results from a study of its tendon cell treatment for tennis elbow in 25 workers' compensation patients. The data shows Ortho-ATI<sup>TM</sup> reduced pain and increased functionality enabling patients to return to work. A significant 88% of patients were able to return to work and more than 50% of these returned at full capacity following ATI treatment.

The Company is well positioned as a leader in musculoskeletal regenerative medicine, looks forward to the continuing development of its lead products for tendon (Ortho-ATI<sup>TM</sup>) and cartilage (Ortho-ACI<sup>TM</sup>) regeneration, and soft tissue reconstruction (Celgro<sup>TM</sup>), and the continued advancement of its pipeline products and opportunities.

Ph: +61 8 9360 2888 Fax: +61 8 9360 2899 www.orthocell.com.au





# For more information, please contact:

## **General enquiries**

Paul Anderson Orthocell Limited, Managing Director

P: (08) 9360 2888

E: paulanderson@orthocell.com.au

#### Media enquiries

Gavin Lower

Buchan Consulting

P: (03) 8866 1215 M: 0414 796 726

E: glower@buchanwe.com.au

#### **Investor Relations**

Ben Walsh
Buchan Consulting

P: + 61 468 422 865

E: bwalsh@buchanwe.com.au

Ph: +61 8 9360 2888 Fax: +61 8 9360 2899 www.orthocell.com.au



Rule 4.7B

# Appendix 4C

# Quarterly report for entities admitted on the basis of commitments

Introduced 31/3/2000. Amended 30/9/2001, 24/10/2005.

Name of entity

# ORTHOCELL LIMITED

ABN

57 118 897 135

Quarter ended ("current quarter")

31 DECEMBER 2015

#### Consolidated statement of cash flows

		Current quarter	Year to date
Cash flows related to operating activities			(6 months)
		\$A	\$A
1.1	Receipts from customers – inclusive of GST	238,276	658,012
1.2	Payments for suppliers and employees – inclusive of GST	(1,480,123)	(3,097,351)
1.3	R&D tax rebate	-	-
1.4	Export Market Development Grant received	-	-
1.5	License fees received	-	-
1.6	Interest received	14,740	28,723
	Net operating cash flows	(1,227,107)	(2,410,616)
Cash f	lows related to investing activities		
1.5	Payment for acquisition of:		
1.0	(a) intellectual property	(119,351)	(187,357)
	(b) property, plant & equipment	(19,236)	(39,572)
	Net investing cash flows	(138,587)	(226,929)
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1.6	Total operating and investing cash flows	(1,365,694)	(2,637,546)
	Cash flows related to financing activities		
1.7	Proceeds from issues of shares	4,326,862	4,326,862
1.8	Payments for share equity costs	(358,091)	(358,091)
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	Net financing cash flows	3,968,771	3,968,771
	Net increase (decrease) in cash held	2,603,077	1,331,225
1.9	Cash at beginning of quarter/year to date	3,502,256	4,774,108
1.10	Cash at end of quarter	6,105,333	6,105,333

<sup>+</sup> See chapter 19 for defined terms.

# Payments to directors of the entity and associates of the directors Payments to related entities of the entity and associates of the related entities

		Current quarter \$A
1.11	Aggregate amount of payments to parties included in item 1.2	257,269
1.12	Aggregate amount of loans to the parties included in item 1.2	-
1.13	Explanation necessary for an understanding of the transactions	
	Executive remuneration and non-executive director fees and consulting fees	257,269

#### Non-cash financing and investing activities

2.1	Details of financing and investing transactions which have had a material effect on consolidated assets
	and liabilities but did not involve cash flows

Not applicable
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2.2 Details of outlays made by other entities to establish or increase their share in businesses in which the reporting entity has an interest

Not applicable	
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#### Financing facilities available

Add notes as necessary for an understanding of the position. (See AASB 1026 paragraph 12.2).

		Amount available	Amount used
		\$A	\$A
3.1	Loan facilities	-	-
3.2	Credit standby arrangements	-	-

#### **Reconciliation of cash**

Reconciliation of cash at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows.		Current quarter \$A	Previous quarter \$A
4.1	Cash on hand and at bank	6,105,333	3,502,256
4.2	Deposits at call	-	-
4.3	Bank overdraft	-	-
4.4	Other (Term deposit)	-	-
	Total: cash at end of quarter (item 1.23)	6,105,333	3,502,256

<sup>+</sup> See chapter 19 for defined terms.

Acquisitions and disposals of business entities

Acquisitions $(Item \ 1.9(a))$	Disposals $(Item \ 1.10(a))$
Not applicable	Not applicable
-	-
-	-
-	-
-	-
	(Item 1.9(a))

#### **Compliance statement**

- 1 This statement has been prepared under accounting policies which comply with accounting standards as defined in the Corporations Act (except to the extent that information is not required because of note 2) or other standards acceptable to ASX.
- 2 This statement does give a true and fair view of the matters disclosed.

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Sign here: Date: 29 January 2016

Print name: Simon Robertson Company Secretary

#### **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 wanting to disclose additional information is encouraged to do so, in a note or notes attached to this report.
- 2. The definitions in, and provisions of, *AASB 1026: Statement of Cash Flows* apply to this report except for the paragraphs of the Standard set out below.
  - 6.2 reconciliation of cash flows arising from operating activities to operating profit or loss
  - 9.2 itemised disclosure relating to acquisitions
  - 9.4 itemised disclosure relating to disposals
  - 12.1(a) policy for classification of cash items
  - 12.3 disclosure of restrictions on use of cash
  - 13.1 comparative information
- 3. **Accounting Standards.** ASX will accept, for example, the use of International Accounting Standards for foreign entities. If the standards used do not address a topic, the Australian standard on that topic (if any) must be complied with.

<sup>+</sup> See chapter 19 for defined terms.

#### SUMMARY OF KEY ACTIVITIES DURING THE QUARTER

During the quarter the Company continued to progress the development of its lead products and pipeline opportunities. Activities included pre-clinical and clinical studies and marketing activities to support the sale of its approved cell therapies as well as development and commercialisation of related collagen based medical device technologies with the following milestones noted during the quarter:

- Orthocell received approval in December 2015 for a human clinical study examining the safety and
  effectiveness of its Celgro™ SMRT Graft™ collagen scaffold, used as an augment to the surgical
  repair of the rotator cuff tendon in the shoulder. The study was granted ethics committee approval
  by St John of God Hospital Group and will involve 30 patients in Perth, Western Australia. It will be
  conducted by some of Australia's leading orthopaedic surgeons. This study will commence in
  calendar Q1 2016.
- During the quarter the Company was granted several key patents:
  - o A patent in Canada covering the combination of bio-scaffolds and tenocytes;
  - o Australian patent for the method to manufacture Celgro™ soft tissue reconstructive, collagen based medical device; and
  - o Hong Kong patent for method to manufacture Ortho-ATI™ for the regeneration of damaged tendons.
- In November 2015 the Company raised \$4.4m via a placement to selected institutional investors in the US, Australia and, following shareholder approval received on 27 January 2016, from various directors and officers of the Company. The capital raising was via the placement of 8,979,436 fully paid ordinary shares at an issue price of \$0.493 per share, being a 15% discount to the 15 day VWAP of the Company's shares traded on the ASX in the 15 trading days prior to the date of the announcement (17 November 2015). The Company also issued investors who participated in the placement free attaching unlisted warrants on the basis of 1.35 warrants for each share issued in the placement. The funds raised from the placement will be used to progress the Company's portfolio of products and for working capital purposes.
- Orthocell's regenerative cell therapy treatment, Ortho-ACI<sup>™</sup> was applied to its first patient in Singapore in November 2015. Singapore is the latest international market Orthocell has expanded Ortho-ACI<sup>™</sup> into, following its successful entry to Hong Kong earlier this year where the therapy was used on patients with articular cartilage damage within the knee joint.
- In November 2015 the Company announced initial positive safety and tolerability results for its Celgro<sup>™</sup> collagen-based medical device in a pilot clinical study examining the safety and effectiveness of its Celgro<sup>™</sup> scaffold for the treatment of bone defects around dental implants. The study is designed to demonstrate the Celgro<sup>™</sup> can be used as a barrier membrane to allow bone growth without competition from other connective tissue.
- In October 2015 Orthocell announced the release of new positive results from a study of its tendon cell treatment for tennis elbow in 25 workers compensation patients. The study was a collaboration between the University of Western Australia and leading orthopaedic surgeons Dr Alex O'Beirne from Perth and Dr Jeff Hughes from Sydney. The data shows Orthocell's autologous tenocyte injection treatment, Ortho-ATI<sup>TM</sup>, significantly improved the clinical outcomes of patients with long-term tennis elbow degeneration, showing reduced pain and increased functionality enabling patients to return to work. A significant 88% of patients were able to return to work and more than 50% of these returned at full capacity following ATI treatment.

<sup>+</sup> See chapter 19 for defined terms.

- During the quarter the company presented at numerous leading national and international congresses further supporting the international interest, safety and effectives of its tendon regeneration product (Ortho-ATI<sup>TM</sup>) and cartilage regeneration (Ortho-ACI<sup>TM</sup>) products, as well as its pipeline products. Presentations included:
  - Previously released positive follow up data for the treatment of recalcitrant tendon injuries in the hip (2 year data) and the elbow (4.5 year data) at the 16th Biennial Congress of the South African Sports Medicine Association;
  - o Positive two year follow up data for Ortho-ACI<sup>TM</sup> treatment for articular cartilage defects of the knee and ankle at two leading regional orthopaedic association annual scientific meetings in Brisbane (Australian Orthopaedic Association) and Singapore (Singapore Orthopaedic Association);
  - o Previously announced "tendon outside the body" tendon bioreactor work at the Australian Orthopaedic Association; and
  - o Previously released positive data around its Ortho-ATI<sup>TM</sup> treatment for degenerate tendon and pipeline opportunities at the international stem cell meeting in the US and Barcelona.