

## Quarterly Cash Flow Report – March 2016

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

Orthocell is a commercial-stage, regenerative medicine company focused on regenerating mobility for patients and our ageing population by developing products for a variety of tendon, cartilage and soft tissue injuries. Orthocell's portfolio of products include TGA-approved 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, Orthocell announced issuance of a US patent for cell-factory derived bioactive molecules for the generation of tissue specific growth factors to enhance soft tissue regeneration. This technology is one of the exciting pipeline products for the Company and strongly complements the existing tendon and cartilage regeneration products that are currently marketed.

In January 2016, the Company presented at the 3rd Melbourne International Hip Arthroscopy meeting. Orthocell's presentation highlighted the previously released positive two-year follow up data for the treatment of recalcitrant tendon injuries in the hip. The pilot study investigated the effect of Ortho-ATI™ in 13 patients who had failed all previous treatment attempts with an average symptom range of 33 months. All patients were assessed by an independent therapist out to two years and demonstrated a statistically significant improvement in pain and function at three months, which was maintained out to 24 months.

In March 2016, the Company announced the appointment of Professor Rocky Tuan to its Medical and Scientific Advisory Board (MSAB). The MSAB provides valuable expertise to Orthocell as it expands its unique tendon and soft tissue specific growth factors and laboratory manufactured human tendons. Dr Tuan is a widely published and respected expert in Regenerative Medicine and stem cells. He is currently the Director of the Centre for Military Medicine Research.

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

Notable near term milestones for Celgro™ include commencement of further clinical trials to expand indications and a CE Mark submission, targeting approval in 2016 for the right to market and sell the collagen scaffold in the EU to enhance guided bone regeneration within the jaw. Ortho-ATI™ development includes the pre-investigational new drug application meeting with the US Food and Drug Administration for US regulatory guidance.





## For more information, please contact:

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# 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 MARCH 2016

### Consolidated statement of cash flows

		Current quarter	Year to date (9 months)
		\$A	\$A
<b>Cash flows related to operating activities</b>			
1.1	Receipts from customers – inclusive of GST	187,806	845,818
1.2	Payments for suppliers and employees – inclusive of GST	(1,309,670)	(4,407,020)
1.3	R&D tax rebate	-	-
1.4	Export Market Development Grant received	-	-
1.5	License fees received	-	-
1.6	Interest received	17,497	46,220
	<b>Net operating cash flows</b>	<b>(1,104,367)</b>	<b>(3,514,982)</b>
<b>Cash flows related to investing activities</b>			
1.5	Payment for acquisition of:		
	(a) intellectual property	(40,519)	(227,877)
	(b) property, plant & equipment	(513)	(40,085)
	<b>Net investing cash flows</b>	<b>(41,032)</b>	<b>(267,962)</b>
<b>1.6</b>	<b>Total operating and investing cash flows</b>	<b>(1,145,399)</b>	<b>(3,782,944)</b>
<b>Cash flows related to financing activities</b>			
1.7	Proceeds from issues of shares	100,000	4,426,862
1.8	Payments for share equity costs	(11,674)	(369,766)
	<b>Net financing cash flows</b>	<b>88,326</b>	<b>4,057,096</b>
	<b>Net increase (decrease) in cash held</b>	<b>(1,057,073)</b>	<b>274,152</b>
1.9	Cash at beginning of quarter/year to date	6,105,333	4,774,108
1.10	<b>Cash at end of quarter</b>	<b>5,048,260</b>	<b>5,048,260</b>

+ 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	187,268
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	187,268

**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 \$A	Amount used \$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	5,048,260	6,105,333
4.2 Deposits at call	-	-
4.3 Bank overdraft	-	-
4.4 Other (Term deposit)	-	-
<b>Total: cash at end of quarter</b> (item 1.23)	5,048,260	6,105,333

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+ See chapter 19 for defined terms.

**Appendix 4C**  
**Quarterly report for entities**  
**admitted on the basis of commitments**


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Acquisitions and disposals of business entities

	Acquisitions (Item 1.9(a))	Disposals (Item 1.10(a))
5.1 Name of entity	Not applicable	Not applicable
5.2 Place of incorporation or registration	-	-
5.3 Consideration for acquisition or disposal	-	-
5.4 Total net assets	-	-
5.5 Nature of business	-	-

**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.

Sign here:   
Print name: Simon Robertson  
Company Secretary

Date: 29 April 2016

**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.

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## **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:

- In January 2016, Orthocell announced issuance of a US patent for cell-factory derived bioactive molecules for the generation of tissue specific growth factors to enhance tissue regeneration. The innovative intellectual property is focused on the generation of 'tissue specific' growth factors for the regeneration of cartilage and bone. Growth factors are an important stimulator of soft tissue and bone regeneration and have traditionally been extremely difficult to isolate. The new patent further strengthens Orthocell's pipeline opportunities which are strongly complementary to its current regenerative medicine approaches. This patent will expire in 2027.
- During the quarter the Company presented at leading international congress, the 3<sup>rd</sup> Melbourne International Hip Arthroscopy meeting. Orthocell presented its previously released positive two year follow up data for the treatment of recalcitrant tendon injuries in the hip. The pilot study investigated the effect of Ortho-ATI<sup>TM</sup>. In 13 patients who had failed all previous treatment attempts with an average symptom range of 33 months. All patients were assessed by an independent therapist out to two years and demonstrated a statistically significant improvement in pain and function at three months, which was maintained out to 24 months.
- During the quarter, the Company announced the appointment of Professor Rocky Tuan to its Medical and Scientific Advisory Board (MSAB). The MSAB advises the Company on strategic matters such as clinical research and product development. It provides valuable expertise to Orthocell as it expands its unique tendon and soft tissue specific growth factors and laboratory manufactured human tendons. Dr Tuan is a widely published and respected expert in Regenerative Medicine and stem cells. He is currently the Director of the Centre for Military Medicine Research.

In March 2016, Paul Anderson (CEO, Orthocell) presented at the 28th Annual Roth Capital Partners conference in California highlighting the Company's progress and confirming that the Company is deal ready and positioned for growth. Mr Anderson presented the Company's near term milestones including:

- Celgro<sup>TM</sup>:
  - CE Mark submission being finalised for submission targeting an approval in 2016
  - FDA 510(k) submission planned for late 2016
  - Further clinical trials planned for tendon augmentation and repair and guided bone regeneration in the jaw
  - Orthocell seeking strategic partners and licensing opportunities
- Ortho-ATI<sup>TM</sup>:
  - IND being prepared for US Phase 2 tennis elbow study
  - Partnering discussions ongoing with US and EU potential partners
  - Discussions in Japan underway to leverage abridged approval process

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