

Quarterly Report – June 2023

Perth, Australia – 31 July 2023: Orthocell Limited (ASX: OCC, “Orthocell” or “the Company”) is pleased to release its Quarterly Report for the quarter ended 30 June 2023.

Key highlights for the quarter:

- 1. Orthocell reports increasing quarterly cash inflows and 52.8% growth from previous year**
 - \$3,984,000 cash inflows received in the quarter including receipts from customers of \$645k, interest received of \$177k and an R&D Tax Incentive rebate for the 2022 financial year of \$3.16m
 - Cash inflows for FY23 of \$5.62m including receipts from customers of \$1.87m, interest received of \$590k and the R&D Tax Incentive rebate of \$3.16m, up 52.8% from the previous year (FY22) of \$3.68m
 - Average cash inflow per quarter in FY23 was \$616k (including receipts from customers and interest received), up 60.2% from the average of the previous year (FY22) of \$385k
- 2. Orthocell sells 11,618 more CelGro™ medical devices to distribution partners than forecast**
 - 10,936 Striate+™ units sold to global exclusive marketing and distribution partner, BioHorizons Implant Systems Inc. (BioHorizons) in FY23 - almost 3 x the Company sales forecast
 - 682 Remplir™ units sold to Australian and New Zealand exclusive distributor, Device Technologies (DVT) in FY23 – equates to >1.5 x the Company sales forecast
- 3. Strong balance sheet with \$24.8m cash at bank at the end of the quarter**
 - Well positioned to continue to gain commercial traction with Striate+™ (approved in US, EU/UK and AUS) and Remplir™ (approved in AUS) in existing markets and funded to gain regulatory approval of Remplir™ in the US
- 4. Appointment of experienced executive, Mr John Van Der Wielen, as independent non-executive chairman**
 - Mr Van Der Wielen has more than 35 years of global experience in wealth management, private banking, investments, and health insurance and is a highly regarded healthcare executive, who is ideally suited to advance the commercialisation of Orthocell’s unique medical devices and cellular therapies
- 5. Inaugural Orthocell Nerve Transfer and Reconstruction Symposium successfully completed**
 - Orthocell brought together an internationally recognised faculty who shared their collective experience in peripheral nerve repair and regeneration with 20 key orthopaedic and plastic surgeons in attendance
 - Up to 70 orthopaedic and plastic surgeons now using Remplir™ in peripheral nerve repair surgeries across Australia and New Zealand
- 6. Nerve repair study for US regulatory approval commenced and on track for completion 1Q CY24**
 - Study provides information regarding mechanism of action that is not possible to collect in human clinical trials and will support product marketing initiatives, as well as international regulatory approval and reimbursement strategies.



Orthocell Managing Director, Paul Anderson, said: “We are delighted to welcome John to the Orthocell Board. He is a globally recognised executive with a passion for supporting innovative life science companies who are growing into significant international success stories. John’s appointment follows the addition of Dr Ravi Thadhani to the Board, as well as Professor Christopher Dy and Professor David Brogan to the Medical Science Advisory Board. These appointments add significant depth to our Board, US specialist team and our ability to execute on our commercialization plans.”

“I am also very pleased with the ramp up of Striate+™ and Remplir™ product sales in the US and Australia, since market launch in November 2022. Product sales are significantly higher than expected and it is a testament to the quality of our Australian manufactured products and distribution partners.”

“Our team continues to work alongside our partners, assisting with education, marketing and establishment of key accounts. We are focussed on building long term mutually beneficial relationships with our distribution partners, and I look forward to what is shaping up to be a great year ahead for the Company.”

Corporate and Cashflow Update

Appointment of Independent Non-Executive Chairman John Van Der Wielen

On 1 June 2023 Orthocell appointed experienced executive, Mr John Van Der Wielen, as independent Non-Executive Chairman. Mr Van Der Wielen has over 35 years’ international experience in wealth management, private banking, investments, and insurance, in the UK, Luxembourg, Malaysia and Australia. Most recently Mr Van Der Wielen was the CEO and Managing Director of HBF Health Ltd for over five years. HBF has revenue of over \$1.6 billion and in a recent independent consumer survey, was named Australia’s most trusted brand in private health insurance.

Mr Van Der Wielen has also held numerous directorships and advisory positions, including roles as Senior Adviser to Blackstone - the world’s largest alternative asset manager - with \$991B in assets under management. Mr Van Der Wielen has significant expertise overseeing and chairing large funds management and investment committees, as well as leading M&A transactions, integrations and restructuring programs. Mr Van Der Wielen brings a wealth of experience in corporate strategy, implementing international growth initiatives and engagement of strategic investors in diverse industries including healthcare, financial services and large superannuation, pension and investment portfolios.

Mr Van Der Wielen is currently Non-Executive Director, of the Blackstone owned, Crown Resorts and Chair of Crown Perth, and Non-Executive Director of the Royal Flying Doctor Service WA. He is a Senior Adviser to Applan Capital Advisory LLP and was recently appointed by the Western Australian Government to Chair its Future Health Research and Innovation Fund (FHRI). The FHRI is a sovereign wealth fund, with a purpose is to improve, through research and innovation, the health and prosperity of Western Australians, the sustainability of the health system and to advance the State’s standing, as a leader in research and innovation.

Cashflow update and FY23/22 comparison

During the quarter Orthocell received cash inflows of \$3,984,000 (including receipts from customers of \$645k, interest received of \$177k and an R&D Tax Incentive rebate for the 2022 financial year of \$3.16m). Most of the expenditure for the quarter was allocated to commercial and R&D related activities. The Company reported a net cash inflow in operating activities for the quarter of \$703,326. At the end of the quarter, Orthocell held a cash balance of A\$24.8m. Orthocell’s strong cash position enables the Company to drive further development of its Remplir™ nerve product and pipeline of regenerative medicine products, delivering significant shareholder value.

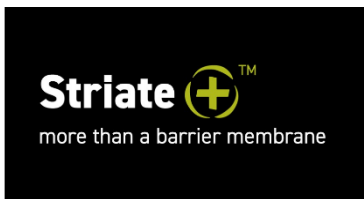


Cash inflows for FY23 were \$5.62m (including receipts from customers, interest received and the R&D Tax Incentive rebate), **up 52.8% from the previous year (FY22) of \$3.68m**. **The average cash inflow per quarter in FY23 was \$616k** (including receipts from customers and interest received), **up 60.2% from the average of the previous year (FY22) of \$385k**. This strong increase in cash inflows is underpinned by the high quality of our Australian manufactured products and performance of distribution partners during their first year in market.

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

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, as well as wider applications in general surgical and soft tissue reconstructive applications. CelGro™ medical devices, including Striate+ and Remplir are manufactured by Orthocell at its quality-controlled facility in WA, using the Company's proprietary SMRT™ manufacturing technology. A facility upgrade to increase manufacturing capacity to >100,000 units per year, was completed in December 2022.



Striate+™ for dental bone and tissue repair

Striate+™ is a market leading resorbable collagen membrane used in guided bone and tissue regeneration procedures. Clinical studies have shown Striate+™ supported transition from a two-stage to a single-stage dental procedure, reducing the procedure time and recovery periods by several months. This is of significant interest to patients and clinicians, due to

potential improvements in efficiency and efficacy of dental procedures. Its uptake is expected to be driven by surgeons' preference for high quality, easy to use devices facilitating better patient outcomes.

BioHorizons Implant Systems Inc.

In July 2022, the Company executed a global exclusive licence and distribution agreement with BioHorizons Implant Systems Inc (**BioHorizons**), one of the largest dental implant companies, for its Striate+™ premium dental membrane. In consideration of the license granted, Orthocell received in cash AU \$21,461,686 million¹ net of fees. BioHorizons is part of Henry Schein, Inc. (NASDAQ: HSIC) and a leading global provider of dental implants and tissue regeneration products for dentists and dental specialists. The company has a broad product offering, including dental implants, guided surgery, digital restorations and tissue regeneration solutions for the replacement of missing teeth. BioHorizons' products are available in 90 markets around the world. For more information, visit www.biohorizons.com.

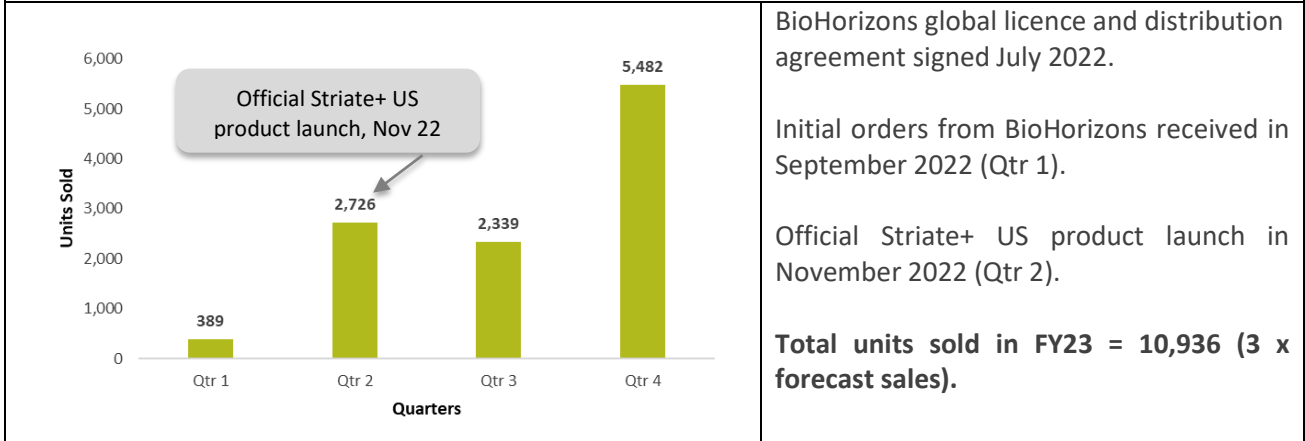
US market entry update

BioHorizons completed a US product launch of Striate+ in November 2022, with a focus on supplying existing Key Opinion Leader accounts and high-profile dental surgeons with this leading dental membrane. The ramp up of product sold during the first period (FY23) has been significantly better than expected. Following discussions with BioHorizons, the Company forecast ~4,000 Striate+ units to be sold in FY23. **Actual sales to BioHorizons in FY23 has been 10,936 units, which equates to almost 3 x the original forecast.**

¹ After transaction costs and assuming 1 United State Dollar is equal to 1.45 Australian Dollars



Figure 1 – Striate+ FY23 Quarterly Sales (# units)



During the quarter, the Company continued to assist BioHorizons’ sales and marketing team with US promotional activities including attendance at the recent Academy of Osseointegration annual meeting, held in Phoenix, AZ (March 16-18, 2023). The annual meeting was attended by almost 2,000 dental surgeons and included Striate+™ hands on workshops, scientific presentations and commercial exhibits.

The Company also progressed the launch of a private label called “Perform collagen membrane” (Striate+ product branded as Perform) with a subsidiary of Henry Schein. The Henry Schein subsidiary plans to launch Perform at the American Association of Oral and Maxillofacial Surgeons (AAOMS) meeting in San Diego, Calif (September 18, 2023). The subsidiary will market and distribute Perform on the same terms and conditions in the BioHorizons global licence and distribution agreement. Adding the subsidiary to the list of US distributors, will increase the representation of the product and assist in servicing a wide range of dental customers in the US.

EU/UK and AUS market entry

During the quarter, the Company and BioHorizons progressed entry into the EU and UK markets. The Company attended the Oral Reconstruction Global Symposia in Rome, IT (May 18-20) to grow awareness of Striate+, the new leading dental membrane coming to market. In addition, BioHorizons submitted their first purchase order to supply Key Opinion Leaders and key accounts and is planning a product launch in 3Q CY2023.

BioHorizons is also progressing well with Australian market entry and establishment of key accounts. The Company is assisting BioHorizons’ sales and marketing team with education and promotional activities targeting the growth of KOL accounts in major Australian cities.



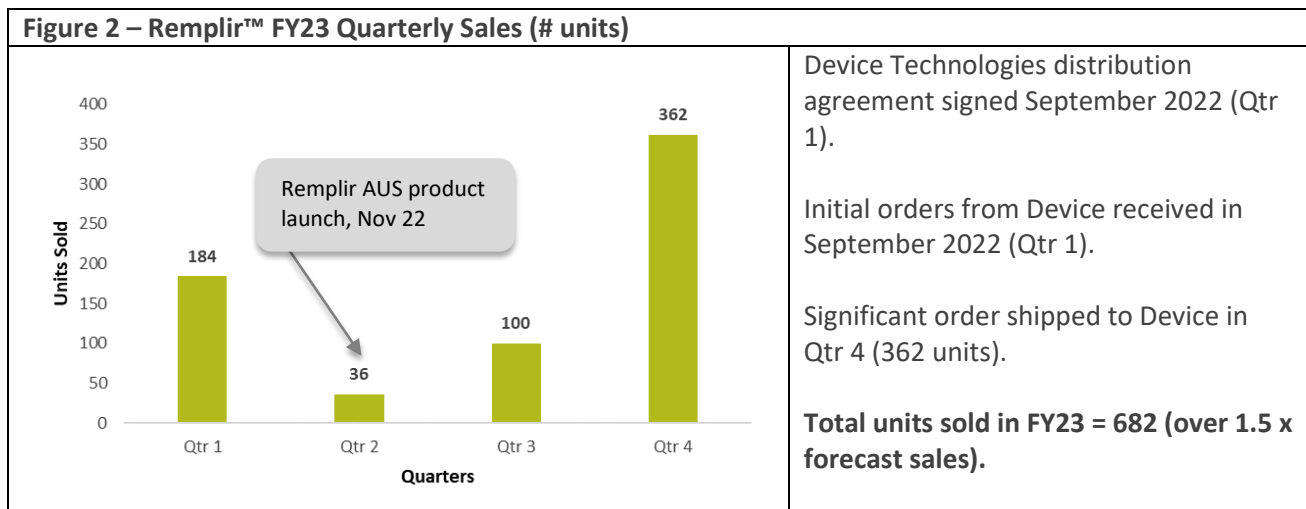
Remplir™ for nerve regeneration

Remplir™ is a collagen nerve wrap used in the repair of peripheral nerve injuries. It provides compression-free protection to the nerve, generating an ideal microenvironment to aid nerve healing. Remplir™ is manufactured using the Company’s SMRT™ manufacturing technology to preserve the collagen structure for optimal tissue integration. Remplir™ is proving to be an important step forward in the improvement

of nerve repair surgery. Its ease of use, consistent and predictable high-quality outcomes, which are achieved in a shorter timeframe compared to other methods, will empower surgeons to improve the lives of people navigating these complex injuries.



The Company appointed Device Technologies (DVT) as the exclusive distributor of Remplir™ across Australia and New Zealand in September 2022 and have been working with DVT to establish key accounts with leading plastic, reconstructive and orthopaedic specialists in Australia and New Zealand. First orders of Remplir™ were shipped to DVT in Qtr 1 FY23 and a significant order of 362 units shipped in Qtr 4 FY23. See Figure 2. **The ramp up of product sold during the FY23 has been significantly better than expected, with approximately 70 orthopaedic and plastic surgeons now using Remplir™ in peripheral nerve repair surgeries across Australia and New Zealand.** Following discussions with DVT, the company forecast ~400 Remplir™ units to be sold during the period. **Actual sales to DVT have been 682 units, which equates to almost >1.5 x the original forecast.**



Orthocell has also assisted DVT with a series of targeted Remplir™ education and promotional events, including the completion of a series of surgeon engagement roadshows in Brisbane, Sydney, Melbourne and Adelaide during the quarter. Orthocell also completed its inaugural **Nerve Transfer and Reconstruction Symposium on 30 June 2023**. The event brought together an internationally recognised faculty who shared their collective experience in peripheral nerve repair and regeneration with 20 key orthopaedic and plastic surgeons in attendance. The R&D team at Orthocell was particularly pleased to have the opportunity to connect with experienced collaborators from Washington University - Dr Regis O’Keefe, Chair of the Department of Orthopaedic Surgery, Dr David Brogan and Dr Christopher Dy - who shared their unique insights in the field of nerve reconstruction and repair. Dr Brogan and Dr Dy recently joined Orthocell as Scientific Advisors. A highlight of the day was the surgical skill training workshop chaired by Dr Alex O’Beirne, who demonstrated the use of Orthocell’s nerve repair device, Remplir™ in nerve repair surgery. Dr O’Beirne highlighted how Remplir™ addresses the clinical challenges and complications associated with suturing delicate nerve tissue providing compression-free protection and an ideal microenvironment for nerve regeneration.

Nerve repair study for US regulatory approval

On 18 April 2023, Orthocell announced the commencement of a comparator study as part of a comprehensive pre-clinical and clinical development program in nerve repair and regeneration. The study provides information regarding mechanism of action that is not possible to collect in human clinical trials. The outcomes



from the study will support product marketing initiatives and international regulatory approval and reimbursement strategies for Remplir™.

This preclinical study will be conducted by Professor Bill Walsh, Director of Surgical and Orthopaedic Research Laboratories (SORL) at the Prince of Wales Hospital in Sydney and the University of New South Wales. The Company anticipates study completion in Q1 2024. For more information [click here](#).

The Company also continues to work closely with US regulatory advisers, to evaluate opportunities for expedited approval of Remplir™ for nerve regeneration.

Advanced Cellular Therapies

Orthocell cell therapies harvest autologous cells from the same tissue that requires repair. A piece of healthy tissue is collected by a surgeon and transported to the Orthocell laboratory. The cells are grown in the laboratory over a few weeks until there is enough to implant. Cells are assessed for purity, potency and identity before being returned to the patient, ensuring high quality tissue repair.



OrthoATI™
for regeneration of human tendon

OrthoATI™

OrthoATI™ is a world-leading cell therapy in development for the treatment of chronic degenerative tendon injuries (tendinopathy/tendonitis). OrthoATI™ 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\$7.7bn² and growing.

The Company is currently conducting a clinical trial focussed on treatment of tennis elbow. The study is fully recruited and the last patient received treatment in May 2022. Outcomes from the study are anticipated to be released following the last patient 12 month follow up (3Q CY 2023) and will provide pivotal data for an application to the Therapeutics Goods Administration (TGA) for inclusion on the Australian Register of Therapeutic Goods (ARTG).

The Company has been progressing its US commercialisation plans including investigations into technology scale up, FDA engagement and commercial preparation activities being to support a Phase 2b randomised controlled study for FDA submission.

Release authorised by:

Paul Anderson
Managing Director, Orthocell Ltd

² Addressable market estimate was developed by the Company using reports from US healthcare databases and referenced papers of studies conducted both within and outside the US



Appendix 4C

Quarterly report for entities subject to Listing Rule 4.7B

Name of entity

Orthocell limited

ABN

57 118 897 135

Quarter ended ("current quarter")

30 June 2023

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	645	1,872
1.2 Payments for:		
(a) research & development (including allocated staff costs)	(1,800)	(6,978)
(b) product manufacturing and operating costs	(746)	(2,184)
(c) marketing, business development & investor relations	(195)	(684)
(d) leased assets	(1)	(3)
(e) staff costs (other than R&D staff)	(292)	(1,230)
(f) administration & corporate costs	(247)	(1,374)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	177	590
1.5 Interest & other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants & tax incentives received	3,162	3,162
1.8 Other (contract revenue net of fees)	-	21,462
1.9 Net cash from / (used in) operating activities	703	14,633
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant & equipment	(10)	(619)
(d) investments	-	-
(e) intellectual property	(28)	(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)	-	-
2.6 Net cash from (used in) investing activities	(38)	(672)

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)	-	-
3.2 Proceeds from issue of convertible debt securities	-	-
3.3 Proceeds from exercise of share options	-	-
3.4 Transaction costs related to issues of equity securities, or convertible notes	-	-
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 (lease payments)	(53)	(165)
3.10 Net cash from / (used in) financing activities	(53)	(165)

4. Net increase / (decrease) in cash & cash equivalents for the period		
4.1 Cash & cash equivalents at beginning of period	24,206	11,022
4.2 Net cash from / (used in) operating activities (item 1.9 above)	703	14,633
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(38)	(672)
4.4 Net cash from / (used in) financing activities (item 3.10 above)	(53)	(165)
4.5 Effect of movement in exchange rates on cash held	-	-
4.6 Cash & cash equivalents at end of period	24,818	24,818

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	6,818	2,206
5.2 Term deposits	18,000	22,000
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)	24,818	24,206

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	446
6.2 Aggregate amount of payments to these parties included in item 2	-
<i>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</i>	

7. Financing facilities available	Total facility amount at quarter end \$A'000s	Amount drawn at quarter end \$A'000s
<i>Note: the term 'facility' includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the position.</i>		
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 Total financing facilities	-	-

7.5 **Unused financing facilities 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)	703
8.2 Cash and cash equivalents at quarter end (item 4.6)	24,818
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	24,818
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	N/A

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:

- 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

- 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

- 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

- 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.

Date: 31-Jul-23

Authorised by: The Board of Orthocell Limited
(Name of body or officer authorising release - see note 4)

Notes

- 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.
- 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.
- 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.
- 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".
- 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.

For more information, please contact:

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About Orthocell Limited

ACN 118 897 135

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Orthocell is a regenerative medicine company focused on regenerating mobility for patients by developing products for the repair of a variety of bone and soft tissue injuries. Orthocell's portfolio of products include CelGro™, a collagen medical device which facilitates tissue reconstruction and healing in a variety of dental and orthopaedic reconstructive applications. Striate+™ was the first product approved for dental GBR applications, is cleared for use in US FDA (510k), Australia (ARTG) and Europe (CE Mark) and is distributed globally by BioHorizons Implant Systems Inc. Remplir™, for peripheral nerve reconstruction, recently received approval and reimbursement in Australia and is distributed exclusively by Device Technologies in the Australian market SmrtGraft™, for tendon repair, is available in Australia under Special Access Scheme or participation in a clinical trial. The Company's other major products are autologous cell therapies which aim to regenerate damaged tendon and cartilage tissue. Orthocell is accelerating the development of its tendon cell therapy in the US with technology transfer, manufacturing scale up and FDA engagement in advance of a randomised controlled study under FDA supervision.

For more information on Orthocell, please visit www.orthocell.com or follow us on Twitter [@OrthocellLtd](https://twitter.com/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 its 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.

