

Orthocell receives \$3.05m R&D tax incentive refund

- Orthocell receives further boost to cash reserves with a \$3.05 million R&D Tax Incentive refund.
- The Company now holds \$22.25 million cash at bank following the recent \$3.5 million strategic placement and receipt of the R+D Tax rebate.
- Orthocell is well funded for its current global market expansion strategy and beyond the pivotal US product registration for Remplir™ expected in Q1 CY25.
- Top-line results from US FDA Remplir™ nerve repair study expected in Q3 CY24, and Orthocell remains on schedule to submit its US 510(K) market authorisation application in Q4 CY24 with progression into sales soon thereafter.
- Remplir has the potential to become the leading device in the US in an addressable market estimated to be worth more than US\$1.1 billion per annum¹

Perth, Australia; 15 April 2024: Regenerative medicine company Orthocell Limited (ASX:OCC, “Orthocell” or the “Company”) is pleased to announce it has received a Research and Development (R&D) Tax Incentive refund of A\$3,051,483 for the financial year 2022/2023.

The receipt of \$3.05 million R&D Tax Incentive refund follows the recent \$3.5 million strategic placement underpinned by prominent investors Mr Chris Ellison, Mr Rod Jones, Mr Michael Malone, the McCusker Family and the Merchant Biotech Fund, which significantly strengthened the Company’s share register. Other recent milestones achieved by the Company include the restructure of the Orthocell Board including the addition of two new high profile Independent Directors, Professor Fiona Wood AM (appointed October 2023) and the Hon Kim Beazley AC (appointed January 2024); and solidifying a long-term partnership with University of Western Australia exchanging all royalty entitlements for shares in Orthocell.

Orthocell Chair, John Van Der Wielen, said: “Orthocell now holds \$22.25 million in cash, has no debt and is free from any royalty payment obligations. I’m energised by the path forward for this Company and look forward to assisting the team to execute its global market expansion strategy – which includes accelerating the Remplir™ nerve repair US market access program and OrthoATI™ partnering activities in the USA. We remain resolutely focused on execution now, to scale the reach and impact of these world-class medical products – a milestone for Australia’s innovation sector at large.”

The R&D Tax Incentive is an Australian Government program to support Australian companies to undertake R&D activities in Australia, under which eligible companies can receive cash rebates of up to 48.5% of eligible expenditure on R&D activities.

Release authorised by Managing Director Orthocell Ltd, Paul Anderson.
For more information, please contact:

¹ US 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.

General & Investor enquiries

Paul Anderson
Orthocell Limited
Managing Director

P: +61 8 9360 2888

E: paulanderson@orthocell.com.au

Media enquiries

Haley Chartres
HACK Director

P: +61 423 139 163

E: haley@hck.digital

About Orthocell Limited

ACN 118 879 135

Registered Office – Building 191 Murdoch University, 90 South Street, Murdoch WA 6150 Australia

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™ platform of collagen medical devices which facilitate 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 and FDA engagement to confirm the path to the US market and prepare for partnering discussions.

For more information on Orthocell, please visit www.orthocell.com 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 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.