

Market Announcement

29 November 2024

Orthocell Limited (ASX: OCC) - Trading Halt

Description

The securities of Orthocell Limited ('OCC') will be placed in trading halt at the request of OCC, pending it releasing an announcement. Unless ASX decides otherwise, the securities will remain in trading halt until the earlier of the commencement of normal trading on Tuesday, 3 December 2024 or when the announcement is released to the market.

Issued by

ASX Compliance



29 November 2024

ASX Compliance Australian Securities Exchange Level 40, Central Park 152-158 St George's Terrace PERTH WA 6000

By email: tradinghaltsperth@asx.com.au

Request for Trading Halt

Orthocell Limited (ASX: OCC, "Orthocell" or the "Company") requests that its securities be placed into an immediate trading halt.

In accordance with ASX Listing Rule 17.1, the Company provides the following information in relation to this request:

- (a) the trading halt is requested pending an announcement by the Company regarding the results of the regulatory study required for an application to the FDA to gain market approval of Remplir in the US;
- (b) the Company requests that the trading halt remain in place until the earlier of the Company making an announcement and the opening of trading on Tuesday, 3 December 2024;
- (c) the Company is not aware of any reason why the trading halt should not be granted; and
- (d) the Company is not aware of any other information necessary to inform the market about the trading halt.

Release authorised by the Board of Orthocell Limited.

For more information, please contact:

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About Orthocell Limited

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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™ 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 @Orthocell.td 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," "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.