

Orthocell signs Striate+™ global exclusive license and manufacturing agreement with BioHorizons

- Orthocell signs a Striate+™ global exclusive licence and manufacturing agreement with BioHorizons Implant Systems Inc. (BioHorizons), one of the largest dental implant companies in the world
- In consideration for the license granted, BioHorizons agrees to pay Orthocell AU \$23.1 million¹ (USD \$16 million)
- Orthocell will grant BioHorizons an exclusive licence of intellectual property (IP) relating to Striate+™, a resorbable collagen membrane, manufactured by Orthocell, used for dental guided bone and tissue regeneration procedures
- Orthocell will supply BioHorizons with Striate+™ products embodying the IP and grant exclusive distribution rights of those products globally
- BioHorizons will market and distribute Striate+™ alongside its innovative and evidence-based dental implants and tissue regeneration products, to continue to improve the life of patients with missing teeth

Perth, Australia; 27 June 2022: Regenerative medicine company Orthocell Limited (ASX:OCC, “Orthocell” or the “Company”) is pleased to announce it has entered into an exclusive patent and trademark license agreement (**Licence Agreement**) and an exclusive distribution and supply agreement (**Distribution Agreement**) with BioHorizons Implant Systems Inc., a Delaware corporation (**BioHorizons**), under which Orthocell will grant BioHorizons an exclusive licence of two patent families covering a collagen scaffold for cell growth and a method for producing a collagen membrane, associated patent applications, improvements and know-how and the Striate+ trademark (together, the **Agreements**).

The licence relates to the Striate+™ products for dental and oral-maxillofacial procedures (the **Field**). The term of the licence is linked to the term of the supply and distribution agreement (25 years) (**Term**). In consideration for the exclusive licence, BioHorizons will pay Orthocell AU \$23.1 million¹ (USD \$16 million) within two business days of the date of execution.

Commenting on the Agreements, President and CEO of BioHorizons, Steve Boggan, said: “We are very pleased to partner with Orthocell to offer our valued customers a dental membrane with excellent handling properties and regenerative potential. Striate+™ will be a highly complementary addition to our global biomaterials product portfolio for dental tissue regeneration.”

Orthocell Managing Director Paul Anderson, said: “BioHorizons is a leading global provider of dental implant and tissue regenerative products with specialist capabilities and resources to expand the marketing, promotion and supply of Striate+™ worldwide. We are delighted to be working with BioHorizons which has established relationships with dentists and dental specialists and a successful track record in driving the market entry of high-quality products.

“The Agreements with BioHorizons represent a significant milestone for Orthocell and provide further external commercial and technical validation of the CelGro™ collagen scaffold platform, from which the Striate+™ dental products were developed.”

¹ Before transaction costs and assuming 1 United State Dollar is equal to 1.44 Australian Dollars



Striate+™ is a market leading resorbable collagen membrane used in guided bone and tissue regeneration procedures. Its uptake is expected to be driven by surgeons' preference for high quality, easy to use devices facilitating better patient outcomes. Clinical studies² have shown Striate+™ supported transition from two-stage to single-stage dental procedures, reducing the procedure time by several months. This is of significant interest to patients and clinicians due to potential improvements in efficiency and efficacy of dental procedures.

BioHorizons, Inc. 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 biohorizons.com.

Specific Terms of the Agreements

BioHorizons will market and distribute Striate+™ alongside its innovative and evidence-based dental implants and tissue regeneration products to continue to improve the life of patients with missing teeth.

Orthocell will manufacture and supply BioHorizons with quantities of Striate+™ products that embody the licensed IP and grant BioHorizons exclusive distribution rights in respect of those products in the Field. Striate+™ is manufactured by Orthocell at its quality-controlled Good Manufacturing Practices (GMP) licensed facility in WA, using the Company's proprietary SMRT™ manufacturing technology.

To ensure continuous supply and access to the IP, the parties will enter into an escrow arrangement and an IP security agreement. The escrow arrangement allows for the release of know-how to BioHorizons if there is a default by Orthocell under the Distribution Agreement (generally which is not rectified within 60 days of notice by BioHorizons). The IP security agreement allows the Licence Agreement to be registered with local IP offices (including IP Australia and the U.S. Patent and Trade Mark Office).

Either party may terminate the Licence Agreement for material breach if such breach is not cured within 90 days after written notice from the other party. Either party may terminate the Distribution Agreement for material breach if such breach is not cured within 60 days after written notice from the other party.

The Distribution Agreement contains two separate regimes for change of control:

- 1) "Sale Default" which is effectively a change in 50% of voting power or acquisition of at least 50% of ordinary shares of Orthocell, or a sale by Orthocell to an unrelated party (other than BioHorizons, Henry Schein Inc. or any of their Affiliates) of all or substantially all of the assets of Orthocell or of the business required by Orthocell to perform its obligations under the Distribution Agreement, in each case during the first three years of the Distribution Agreement. If this occurs, BioHorizons has a 20-day period following announcement of the proposed transaction (or otherwise becoming aware of the proposed transaction, in the case that Orthocell is no longer listed on the ASX) that would trigger a change of control during which it can claim a refund of the full licence fee (payable two weeks after

² Allan B, Ruan R, Landao-Bassonga E, Gillman N, Wang T, Gao J, Ruan Y, Xu Y, Lee C, Goonewardene M, Zheng M. Collagen Membrane for Guided Bone Regeneration in Dental and Orthopedic Applications. Tissue Eng Part A. 2021 Mar;27(5-6):372-381. doi: 10.1089/ten.TEA.2020.0140. Epub 2020 Sep 10.



completion of the relevant transaction), and the Agreements will automatically terminate. This will be BioHorizons' sole remedy.

- 2) "Supply Default" which is effectively a change in 50% of voting power or acquisition of at least 50% of ordinary shares of Orthocell in favour of a competitor of BioHorizons, or a sale by Orthocell to a competitor of BioHorizons of all or substantially all of the assets of Orthocell or of the business required by Orthocell to perform its obligations under the Distribution Agreement, or a change in manufacturing facilities, in each case during the first seven years of the Distribution Agreement, which results in a failure to supply Striate+™ products by Orthocell that were ordered by BioHorizons before the change of control event. If this occurs, BioHorizons can pursue two of the following three remedies: (i) release of know-how from escrow; (ii) a partial refund of license payments based on the number of anniversaries since the commencement of the Distribution Agreement; or (iii) 12 months' worth of extra supply of Striate+™ products. This doesn't preclude BioHorizons from pursuing other contractual remedies, usual for an agreement of this type, that may be available.

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About Orthocell Limited

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 repair and healing in a variety of dental and orthopaedic reconstructive applications. Striate+™ was the first product approved for dental GBR applications and is cleared for use in US FDA (510k), Australia (ARTG) and Europe (CE Mark). Remplir™, for peripheral nerve repair, recently received approval in Australia (ARTG). 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.au 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.

