

# **Addresses By Chair and Managing Director**

**Perth, Australia; 31 October 2023:** Regenerative medicine company Orthocell Limited (ASX: OCC, "Orthocell" or the "Company") is pleased to attach copies of the addresses to be given by the Chair and Managing Director and CEO at Orthocell's Annual General Meeting (AGM) today.

### Release authorised by:

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### **CHAIR'S ADDRESS**

Fellow shareholders, thank you for joining me today, my first AGM address as your Chair. The 2023 financial year has been pivotal for Orthocell and I look forward to providing you with an update on our progress and next steps. I would like to start with a brief background of my experience and insight into my personal motivations for joining Orthocell. I will then summarise some of the positive corporate changes we have recently implemented since my appointment. This will be followed an operational update from our CEO and MD, Paul Anderson.

### 1) My background

For those that I have not met, I am a senior financial services professional, with over 35 years' international experience in wealth management, private banking, investments, and M&A. I have worked in the UK, Luxembourg, Malaysia and Australia. Most recently I was the CEO of HBF Health Ltd for over five years. HBF has revenue of over 2.0 billion dollars and in a recent independent consumer survey was named Australia's most trusted brand in private health insurance. My other previous executive positions include CEO (UK & International) of Friends Life UK, Managing Director (Wealth) of ANZ, CEO of Clerical Medical, Halifax Life and Heidelberger Leben. My expertise covers chairing large funds management and investment committees, as well as leading on acquisitions, integration and restructuring programs.

### 2) Why did I join Orthocell?

I first came across Orthocell whilst I was CEO at HBF Health and have been monitoring the Company's significant progress. I have a passion for helping WA life science companies succeed and I believe Orthocell is well placed to make a truly meaningful impact on peoples' lives and to build shareholder value. Orthocell has enormous clinical and commercial prospects with its new nerve product, Remplir™, once approved in the USA and Europe. It is a rare opportunity to Chair a company that has no debt, no royalty payment overhang, and a short-term path to US FDA approval.

#### 3) My short-term focus

Since I joined the Board on 29 May 2023, my short-term focus has been on strengthening corporate governance; optimising the balance sheet and increasing revenue control; and building a share register that supports the Company's growth objectives.

### a) Governance has been strengthened

As Chair, part of my role is to ensure we have appropriate corporate governance measures in place that effectively outline how we, as a Board, guide and monitor the Company's business on behalf of its shareholders. As part of strengthening governance, I have completed a review of board composition, independence, tenure and fees to ensure we are positioned to drive our products into global markets and accelerate revenue growth. This has resulted in the strengthening of the Board and focusing on the recruitment of globally experienced Independent Non-Executives.

#### i) Board capability and renewal

The rationalisation of the Board has resulted in the retirement of two Directors, Professor Lars Lidgren and Qi Xiao Zhou. I would like to formally recognise their invaluable contributions over many years.

In other changes, Dr Stewart Washer will move from Executive Director to Non-Executive Director and Professor Fiona Wood AM will commence as an Independent Non-Executive Director.



Professor Wood is one of Australia's most innovative and respected plastic and reconstructive surgeons and researchers. Professor Wood is a former Australian of the year and brings a wealth of experience in navigating pathways for the development and commercialisation of innovative regenerative medicine products, successful international product launches, and engagement of strategic partners in healthcare.

Professor Wood is most notably recognised for developing and commercialising the RECELL "spray on skin" treatment — which has transformed the recovery path for burns victims, now supplied by Avita Medical Inc, a AU\$450M dual listed company with operations in over 30 countries including the US.

All changes will be with effect on 1 November 2023.

### ii) Executive remuneration review and planned adjustments

We have also rebalanced our remuneration framework to further focus executives on generating long-term, sustainable value by delivering on our strategic objectives. In the near-term I will also be reviewing the Executive Team's employee share option plan to ensure we have the right structure in place and to align the Executive Team's total remuneration with the value created for our shareholders.

### b) Balance sheet strength and revenue control

I have been personally leading negotiations with the University of Western Australia (UWA) to buy out all existing and future royalty payments relating to the Company's CelGro™ medical devices and OrthoATI™ tendon cell therapy. In consideration for exchanging the royalty's payable, Orthocell has agreed to issue UWA 1.71 million fully paid ordinary shares in capital of the Company at a deemed issue price of \$0.35 per share. UWA exchanging royalty entitlements for shares in Orthocell reflects the long-term partnership focus of both parties and is positive for future investors. This agreement allows Orthocell to retain all revenue benefits of its Intellectual Property and makes Orthocell more attractive to potential partners and investors. Orthocell is now a debt-free, royalty-free company that can work towards USA approvals and a steady cash flow free of royalty liabilities.

#### *c) Optimising the share register*

Paul and the team have done a great job recently in raising the profile of the Company with institutional investors through the initiation of coverage by two Sydney based broking firms. My role is to assist Paul and the team in consistently promoting the Orthocell story and increasing the percentage of stock held by high quality investors. I believe we present a compelling investment case, and we are starting to gain traction with some high-profile investors buying on market. There is more work to do, but we are clear on the path ahead to optimise the share register, and what it will take to drive upward pressure on the stock price.

### 4) Financial performance

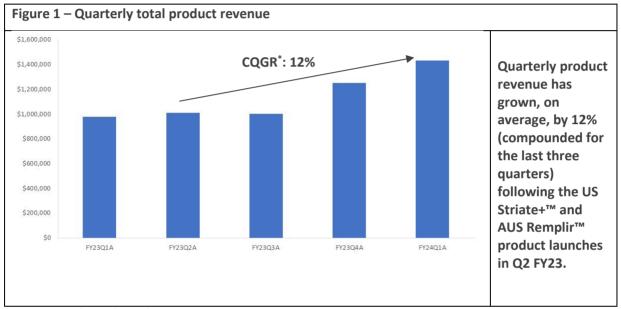
Orthocell reported increasing total revenue to \$5.17 million in FY23, up 186.5% from FY22 of \$1.80 million. This was primarily driven by a 177% growth in product revenue (product sales and Striate+license revenue) to \$4.24 million in FY23 from \$1.53 million in FY22.



I would like to direct your attention to our growing quarterly revenue and in particular the 14% growth in new product sales to \$1.43 million in Q1 FY24 from \$1.25 million in Q4 FY23, up 46% on Q1 FY23 of \$979K (see Figure 1).

Quarterly product revenue has grown on average, by 12% (compounded for the last three quarters) following the US Striate+™ and AUS Remplir™ product launches in Q2 FY23.

Paul will discuss the strong performance of our Distributors in more detail shortly.



\*CQGR = Compound Quarterly Growth Rate

You will have seen from our annual accounts that total expenses rose during the year following increased investment in research and development and higher expenses in administration and corporate areas. We expect total expenses to be similar in FY24 as we allocate appropriate resources to support our nerve US market access program.

### 5) Next Steps

My next order of business will be to bring the Board together to review and refine our corporate strategy. The previous Board has successfully guided the Company through the design of pre-clinical studies to first in-human trials, international regulatory approvals, manufacturing scale-up and global partnering of first products in market. The Company now has many options in front of it to maximise value from its breakthrough regenerative medicine product portfolio.

I now invite Paul Anderson to address the AGM.



### **MANAGING DIRECTOR & CEO ADDRESS**

Thanks John. It is a pleasure to be here with you today. If I may say so, it's been another extraordinary year for the Company, and I am extremely proud of what our team has achieved in FY23. From a major distribution and manufacturing deal, to upgrading our manufacturing capacity and distributors performing ahead of expectations. I am very pleased, and I believe our valued shareholders should be as well. Our achievements in FY23 reinforce my confidence that we have a very bright future. In particular, our nerve and tendon repair products are world-class, and we are in a strong position to dominate global markets.

I would like to take this opportunity to summarise the FY23 highlights.

## **CelGro™ Platform Medical Device**

CelGro<sup>™</sup> is a biological collagen membrane used to augment surgical repair of bone and soft tissue. CelGro medical devices, including our products Striate+<sup>™</sup> and Remplir<sup>™</sup>, are manufactured by Orthocell at its quality-controlled facility in WA, using the Company's proprietary SMRT<sup>™</sup> manufacturing technology. We completed a facility upgrade to increase manufacturing capacity to >100,000 units per year in December 2022.



### Striate+™ for dental bone and tissue repair

Striate+™ is a world-class collagen membrane used in dental guided bone and tissue regeneration procedures. In July 2022, the Company executed a global exclusive licence and distribution agreement for Striate+™ with BioHorizons Implant Systems Inc (BioHorizons), one of the largest dental implant companies.

### **BioHorizon Sales**

In November 2022, BioHorizons launched Striate+™ in the US, with a focus on supplying existing Key Opinion Leader (KOL) accounts and high-profile dental surgeons. The ramp up of product sold during the first 12-month period (01 September 2022 – 30 September 2023) has been significantly better than expected and continues to build momentum. Feedback from US dental surgeons has been phenomenal. This translates to a 17% average quarterly growth rate (compounded for the previous three quarters) since US product launch in Q2 FY23 and a 50% increase in Striate+™ sales in Q1 FY24 since the previous quarter Q4 FY23.

#### Private label launched in the US

In September this year, the Company, in partnership with a subsidiary of Henry Schein, successfully launched perFORM, a private label version of Striate+™, in the US. The Henry Schein subsidiary's agreement with the Company allows it to sell Striate+™ under its own tradename and branding. The Henry Schein subsidiary has an established network of US based dental service organisations (DSO's), which provide consumables to multiple dental practices. Adding the subsidiary to the list of US distributors will increase the representation of Striate+™/perFORM and assist in servicing a wider range of dental customers in the US.

### **EU/UK and AUS market launch**

BioHorizons kicked off its EU and UK launch plans in May 2023 and is actively promoting Striate+™ as the new leading dental membrane delivering high quality dental outcomes for the surgeon and the patient. Recently Orthocell delivered a substantial order of Striate+™ to BioHorizons in Europe to meet its initial KOL and other key account demands. BioHorizons is also targeting key accounts in Australia and the Company is assisting the sales and marketing team with education and promotional activities.





## Remplir<sup>™</sup> for nerve regeneration

Remplir™ is a collagen nerve wrap used in the repair of peripheral nerve injuries. The Company appointed Device Technologies (DVT) as the exclusive distributor of Remplir™ across Australia and New Zealand in September 2022 and has been working with DVT to establish key accounts with leading plastic, reconstructive and orthopaedic specialists in Australia and New Zealand.

### **Device Technologies sales**

DVT officially launched Remplir™ in Australia in November 2022, with a focus on supplying existing othopaedic and plastic reconstructive KOL accounts. The ramp-up of product sold since appointing DVT as distributor has been significantly better than expected with approximately 80 orthopaedic and plastic surgeons now using Remplir™ in peripheral nerve repair surgeries, from facial to upper and lower limb nerves, across Australia and New Zealand. Feedback from the DVT salesforce has been very encouraging, with a 105% average quarterly growth rate (compounded for the previous three quarters) since AUS product launch in Q2 FY23 and a 39% increase in Remplir™ sales in Q1 FY24 since the previous quarter Q4 FY23.

### 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 Company anticipates study completion in Q1 2024 with results to follow. The outcomes from the study will support product marketing initiatives and international regulatory approval and reimbursement strategies for Remplir<sup>TM</sup>.

### US market access program in development

The Company recently attended the 78<sup>th</sup> American Society for Surgery of the Hand annual meeting in Toronto. This meeting provided a strategic opportunity to continue the US KOL engagement program, a critical part of the US market access strategy. The Company also continues to work closely with US regulatory advisers, to evaluate opportunities for expedited approval of Remplir™ for nerve regeneration.



### **OrthoATI™**

OrthoATI™ is a world-leading cell therapy used for the treatment of chronic degenerative tendon injuries. OrthoATI™ can be used alone or in combination with the CelGro™ membrane surgical to regenerate damaged or diseased tendon, and is at the forefront of a large and increasing market opportunity, estimated to be worth >US\$7.7bn¹ and growing. OrthoATI™ is currently a pipeline product, but we are working towards regulatory approval in Australia and the US.

The Company recently completed a clinical trial focused on treatment of tennis elbow. **Outcomes from the study are anticipated to be released 4Q CY2023** 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 to support a Phase 2b randomised controlled study for FDA submission.

<sup>&</sup>lt;sup>1</sup> 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.



### **Investor Relations**

We have been working hard, in particular during FY23, to attract independent analyst coverage, and I am pleased to report we now have two boutique institutional broking firms that have initiated coverage of the Company.

I would like to conclude by thanking our team for their hard work during FY23. What we do matters, and it is our team of highly dedicated people who continue to progress these opportunities every day.

Thank you and I will now hand back to John.

#### **About Orthocell Ltd**

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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, manufacturing scale up and FDA engagement in advance of a randomised controlled study under FDA supervision.

For more information on Orthocell, please visit <a href="www.orthocell.com">www.orthocell.com</a> or follow us on Twitter <a href="www.orthocell.com">@Orthocell.td</a> and LinkedIn <a href="www.orthocell.com">www.linkedin.com/company/orthocell.ltd</a>

### **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 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.