

ASX Announcement



Quarterly Report – September 2025

Perth, Australia; 10 October 2025: Regenerative medicine company Orthocell Limited (ASX: OCC, “Orthocell” or the “Company”) is pleased to release its Quarterly Report for the quarter ended 30 September 2025.

Key highlights for the quarter are as follows:

- **Record revenue for the quarter of \$3.0 million driven primarily by Remplir’s growing market penetration in Australia and Singapore.**
 - September quarter revenue represents an 11% increase over the previous quarterly record of \$2.7 million for the June 2025 quarter.
 - This result is the sixth consecutive quarter of record revenue, with a Compound Quarterly Growth Rate (“CQGR”) of 11% since Q2 FY24.
 - Outstanding result does not yet include material revenue from Remplir sales in the US, which are expected to build during the December 2025 Quarter and grow into 2H FY26.
- **Orthocell maintains robust cash reserves of \$27 million as at 30 September 2025 and is well-positioned for continued commercial expansion.**
- **Remplir rollout in the US\$1.6 billion US market¹ ahead of schedule. Highlights of the Remplir US commercialisation include:**
 - Nerve repair specialist distributor network across 25 states, covering 40% of the US population.
 - First US surgeries completed across multiple hospitals, with over 100 surgeons now introduced to the product. 14 Medical Advisory Board members under contract.
 - 51 Value Analysis Committee (“VAC”) applications lodged with hospitals; 11 approvals already in place. State licenses in progress.
- **First distributor appointed for Remplir in US\$75 million¹ Canadian market.**
 - Exclusive distributorships have been secured for Alberta and British Columbia.
 - Further appointments anticipated for additional provinces.
 - First sales targeted for December 2025 Quarter.

¹ Nerve repair market sizes estimated using referenced papers from both US and OUS databases and studies.

• **Remplir used in nerve-sparing prostate cancer surgery:**

- Globally significant opportunity to reduce the risk of erectile dysfunction and urinary incontinence
- 40 surgical cases undertaken by urologists in Australia.
- Initial patient data expected Q4 CY25.

• **Remplir study results deliver a compelling 81% success rate.**

- Real-world evidence, patient data collected in the study, confirms Remplir as the ideal medical device for connecting severed nerves, protecting damaged nerves, or capping nerve ends after amputation.
- No post-treatment complications or adverse reactions to Remplir were reported in any patient.

• **Executive Leadership Team and Board appointments.**

- The leadership team was strengthened with the appointment of two highly experienced senior executives: Jim Piper as Chief Financial Officer and Adam Wood as Chief Commercial Officer.
- Michael McNulty, former Managing Partner of Deloitte's Perth office appointed as a Non-Executive Director following the retirement of The Hon Kim Beazley AC for health reasons.

Orthocell CEO and MD, Paul Anderson, said: *"We have continued to build strong commercial momentum in the September quarter with another record quarter of sales revenue delivered primarily from Remplir sales in our existing markets in Australia and Singapore.*

"The US rollout of Remplir remains a central operational focus and pleasingly we're well ahead of schedule in this regard. We've seen the first revenue contributions from the US during the quarter from our early surgical cases, and we expect that to build during the December 2025 Quarter and grow into the second half of the financial year.

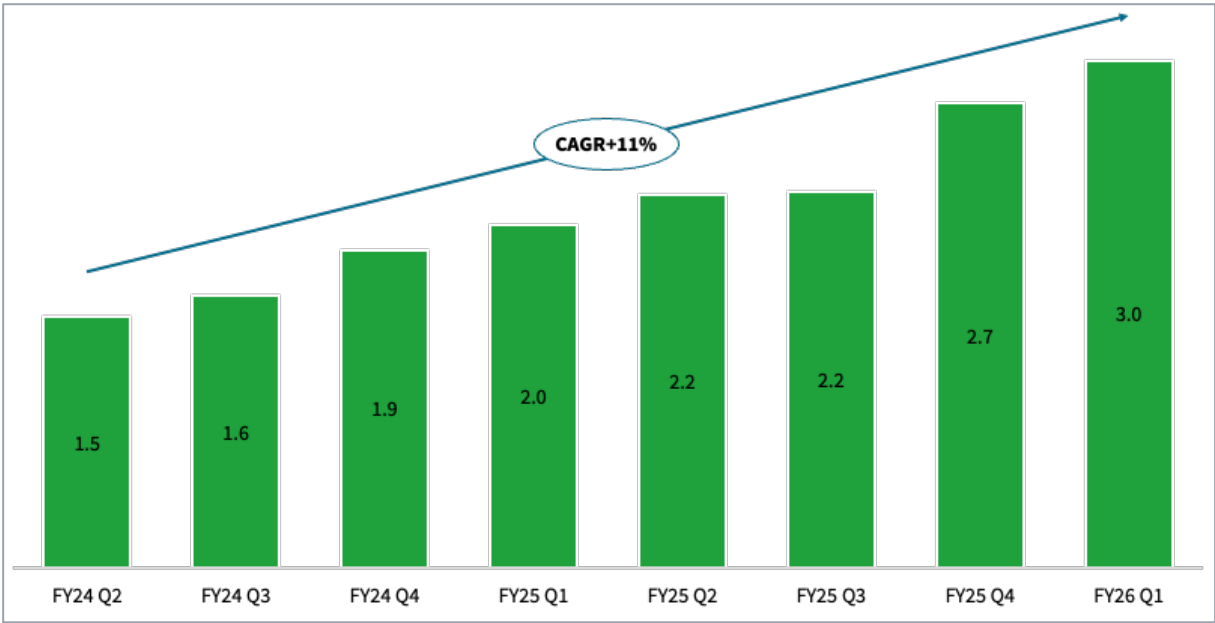
"The appointment of our first distributor in Canada is also a significant step forward in our North American Remplir commercialisation. There are very good synergies for us in that market with our on-the-ground team already in place in the US.

"We're also very excited about the prospects for the use of Remplir in nerve-sparing prostate cancer surgeries. Prostate cancer remains the most diagnosed cancer among men globally and this promising new application has the potential to significantly grow our Total Addressable Market."

Corporate and Financial Commentary

Orthocell reported quarterly revenue of \$3.0 million in the September 2025 Quarter, up 11% on the previous quarterly record of \$2.7 million achieved in the June quarter, and up 50% from \$2.0 million for the same period last year (September 2024 Quarter, Figure 1). Consistent revenue growth demonstrates clear traction with new and existing surgeons, translating to growing sales of the Company’s market-leading products Striate+ and Remplir.

Figure 1: Quarterly revenue



Cash receipts received from customers, inclusive of GST, for the quarter ended 30 September 2025 totalled \$2.4 million, consistent with the Company’s expectations. Net cash outflows from operating activities for the quarter were \$3.0 million. Expenditure was focused on manufacturing, commercial and R&D activities.

At the end of the quarter, Orthocell held a cash balance of A\$27 million. Orthocell’s cash balance positions the Company to continue its strategy of growing sales in existing markets, expanding into the USA, and securing additional strategic international regulatory approvals. Continued revenue growth from the Australian market with Remplir highlights the best-in-class product dynamic and the significant revenue potential of global markets.

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

Release authorised by:

Paul Anderson

Orthocell Ltd CEO and MD

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About Orthocell Limited

ACN 118 897 135

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 a 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 the US, Australia, New Zealand, Singapore, UK, Europe, Canada and Brazil and is distributed globally by BioHorizons Implant Systems Inc. Remplir™, for peripheral nerve reconstruction, recently gained clearance for use in the US. The Company has appointed 15 US distributors and recorded initial sales. The Company's flagship nerve repair product is also approved in Australia, New Zealand and Singapore where it is distributed by Device Technologies Group. Other Remplir approvals include Thailand and Canada. 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.

Appendix 4C

Quarterly report for entities subject to Listing Rule 4.7B

Name of entity		
Orthocell limited		
ABN		Quarter ended ("current quarter")
57 118 897 135		30 September 2025
Consolidated statement of cash flows	Current quarter \$A'000s	Year to date 3 months) \$A'000s
1. Cash flows from operating activities		
1.1 Receipts from customers	2,370	2,370
1.2 Payments for:		
(a) research & development	(1,305)	(1,305)
(b) product manufacturing and operating overheads	(1,681)	(1,681)
(c) marketing, business development & investor relations	(1,421)	(1,421)
(d) leased assets	(1)	(1)
(e) staff costs	(725)	(725)
(f) administration & corporate costs	(840)	(840)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	533	533
1.5 Interest & other costs of finance paid	(7)	(7)
1.6 Income taxes paid	-	-
1.7 Government grants & tax incentives received	30	30
1.8 Other (R&D tax incentive rebate)		
1.9 Net cash from / (used in) operating activities	(3,047)	(3,047)
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant & equipment	(26)	(26)
(d) investments	-	-
(e) intellectual property	-	-
(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	(26)	(26)

Consolidated statement of cash flows		Current quarter \$A'000s	Year to date 3 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	1,427	1,427
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)	(57)	(57)
3.10 Net cash from / (used in) financing activities		1,370	1,370
4. Net increase / (decrease) in cash & cash equivalents for the period			
4.1	Cash & cash equivalents at beginning of period	28,620	28,620
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,047)	(3,047)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(26)	(26)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1,370	1,370
4.5	Effect of movement in exchange rates on cash held	-	-
4.6 Cash & cash equivalents at end of period		26,917	26,917
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	3,417	2,120
5.2	Term deposits	23,500	26,500
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)		26,917	28,620
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		562	
6.2 Aggregate amount of payments to these parties included in item 2		-	
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			
7 Financing facilities available <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>		Total facility amount at quarter end \$A'000s	Amount drawn at quarter end \$A'000s
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)	(3,047)
8.2 Cash and cash equivalents at quarter end (item 4.6)	26,917
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	26,917
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	9

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

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 10 October 2025

Authorised by: Paul Anderson - Managing Director
(Name of body or officer authorising release - see note 4)

Notes

- 1 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.
- 2 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.
- 3 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.
- 4 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".
- 5 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.