Quarterly Report – June 2025

Perth, Australia; 9 July 2025: Regenerative medicine company Orthocell Limited (ASX: OCC, "Orthocell" or the "Company") is pleased to release its Quarterly Report for the quarter ended 30 June 2025.

Key highlights for the quarter:

1. **Record revenue of $9.19m for FY2025 and $2.73 million for the June quarter, underscoring Orthocell's market penetration and sales growth of its flagship nerve repair product Remplir™ in Australia**
   - Revenue for FY2025 up 35.8% on the previous financial year, and revenue for the June quarter up 22.8% on the previous quarterly record of $2.22 million achieved in the March quarter, showing exceptional growth in existing markets.
   - The result is the fifth consecutive quarter of record revenue for the Company and continues Orthocell's quarterly revenue growth trajectory of a Compound Quarterly Growth Rate ("CQGR") of 9.5% over the last 3 years.
   - Importantly, this outstanding result does not yet include revenue from Remplir™ sales in the US, which are expected to gather momentum in the first half of FY26.

2. **Strong cash position retained with A$28.6m cash at bank (no debt).**
   - Orthocell remains well capitalised to continue the global commercialisation roll out of Remplir and Striate+ with cash reserves of A$28.6m, up 38.8% from the previous year's balance of $20.6m.
   - No material capital expenditure required from Orthocell to support the initial US roll out of Remplir.
   - Cost effective sales model adopted with a focus on external distributors throughout global markets and targeted internal on-the-ground staff in the US.

3. **Orthocell's primary focus for the quarter, following US FDA 510(k) clearance on 04 April 2025 for Remplir™, its flagship nerve repair product, was the execution of its US sales roll out plan. The following notable events were achieved:**
   - The Company is now cleared to commence commercial distribution into the globally significant US$1.6 billion[1] nerve repair market which is expected to provide a step change in revenue.
   - Orthocell recorded the first use of Remplir in the US which is a crucial step in the rollout of Remplir in the significant US market, building surgical experience and knowledge of the product that will be key in driving product sales.
   - Rapid establishment of a growing US distributor network of 14 specialist nerve distributors with mature, direct-to-surgeon, hospital and other customer relationships across 25 US states.
   - Successful completion of another study demonstrating that nerve repair with Remplir results in superior regeneration of nerve tissue and earlier return of muscle function, compared to current standard of care, which involves suture-only repair.
   - Orthocell is now well placed to generate first US sales with the first case completed, logistics and sales pathways established and annual medical device manufacturing capacity for 100,000 units in place, and capability for further modularised low capital manufacturing expansion.
   - Significant Remplir™ inventory built up during the quarter.

[1] USA nerve repair market size was estimated using referenced papers from both US and OUS databases and studies

4. **Orthocell expanded regulatory approvals for Remplir in strategically important international markets**
   - Orthocell received regulatory approval to commence sales of Remplir™ in the strategically important markets of Hong Kong, Thailand and Canada.
   - Regulatory approvals received well ahead of expectations demonstrating the quality of the product, the clinical data, and its growing global recognition.
   - Markets outside of the US to be serviced using external specialist distributors with minimal additional internal resources required.
   - Internal resources remain focused on the Remplir rollout in the US market, with in-country representatives making significant progress towards imminent first US sales.

5. **Continued global roll out of Striate via Orthocell's global distribution partner BioHorizons, with Brazilian regulatory approval received in the quarter**
   - Orthocell received regulatory approval from the Brazilian Health Regulatory Agency (Agencia Nacional de Vigilancia Sanitaria or 'ANVISA'), allowing the Company to commence sales of its market-leading dental guided bone regeneration product, Striate+™, in the large and important market of Brazil
   - Brazil is a US$65 million[2] market opportunity and a key part of the wider US$735 million[3] global market the Company is targeting for Striate+ in select jurisdictions
   - Orthocell is working with its exclusive global distribution partner BioHorizons on an initial market launch and expects to commence commercial distribution of Striate+ in 1H CY 2026
   - Regulatory approval in Brazil adds to the growing list of approved markets for Striate+, which includes the US, Europe, UK, Australia, New Zealand, Canada and Singapore

Orthocell CEO and MD, Paul Anderson, said: "This was a landmark quarter for Orthocell following receipt of US FDA 510(k) clearance in early April. We were well prepared in advance of receipt of this approval, however once it came through, we were able to accelerate our progress towards first sales in the US. The key to accessing the US market is striking the right balance between internal resources and external specialist distributors who hold direct relationships with the surgeons and hospitals that are ultimately our customers.

We couldn't be more pleased with the progress achieved through the quarter, which culminated in the first US surgical use of Remplir at the end of June. It's been a significant achievement to get that done within 3 months and is an important catalyst to move towards growing sales, which we expect to ramp over the coming quarters.

It's important to stress, our record result for June quarter was achieved prior to a contribution from Remplir in the US. We've seen excellent take up of Remplir in our existing markets, most notably Australia. We feel this is an endorsement of the market access model that we expect to replicate on a far larger scale in the US."

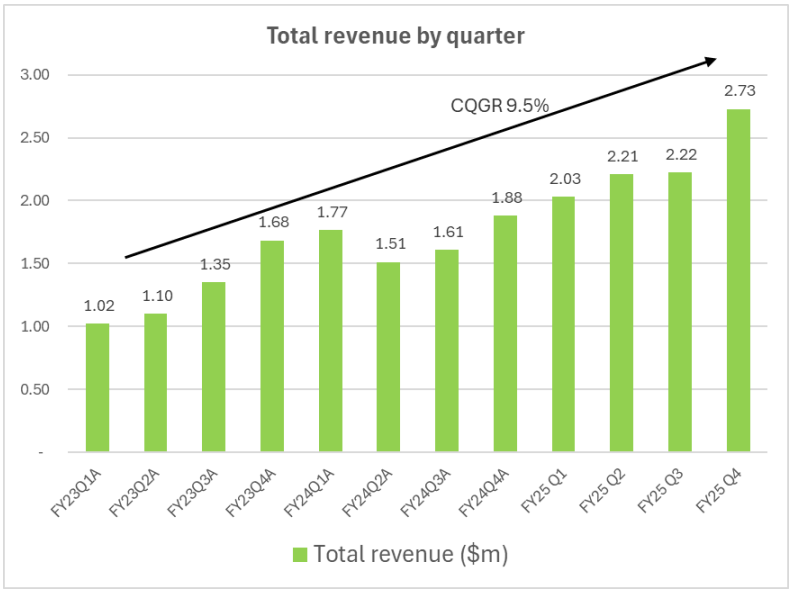
[2] Brazil dental membrane market size was estimated using referenced papers from both US and OUS databases and studies

[3] Addressable markets include AUS, USA, EU/UK, SGP, CAN, BRZ, JAP. Referenced papers were used to estimate procedures per annum. Papers used included both US and OUS databases and studies.

Corporate and financial commentary

Orthocell reported FY2025 annual revenue of $9.19m, up 35.8% on the previous year, and quarterly revenue of $2.73 million in the June 25 Quarter up 22.8% on the previous quarterly record of $2.22 million achieved in the March quarter, and up 45.1% from $1.88 million for the same period last year (June 24 Quarter, Figure 1). Consistently growing revenue shows 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



Quarterly revenue has grown by 9.5% compounded for the last ten quarters following the product launches in Q2 FY23.

Revenue is up 22.8% from $2.22 million in March 25 Quarter to $2.73 million in June 25 Quarter.

*CQGR = Compound Quarterly Growth Rate

Cash receipts received from customers, inclusive of GST, for quarter ended 30 June 2025 totalled $1,337k, consistent with the Company's expectations. Net cash outflows from operating activities for the quarter were $3,541k. Expenditure was focused on commercial and R&D activities.

At the end of the quarter, Orthocell held a cash balance of A$28.6 million. Orthocell's cash balance places the Company in a strong position to continue its strategy to expand into the USA in 2025 and continue lodgement of international regulatory applications. 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.

Collagen Medical Devices

Orthocell's collagen medical devices are manufactured using a proprietary SMRT™ manufacturing process, which is designed to remove all cellular and genetic material while preserving the natural collagen structure. The purified collagen scaffold provides the ideal environment for cellular attachment and proliferation. The devices are completely absorbed by the body, integrating and resorbing into the tissue as it heals with no immunogenic reactions. Consequently, this medical device has a wide and growing range of uses in orthopaedics and other surgical specialities. We call this our *collagen medical device platform* - a family of

products with wide potential for future development. A facility upgrade to increase manufacturing capacity to >100,000 units per year was completed in December 2022.

Striate+™ for dental bone and tissue repair

Striate+ is a market-leading resorbable collagen membrane used in guided bone and tissue regeneration procedures. Clinical studies have shown Striate+ supported transition from a two-stage to a single-stage dental procedure, reducing the procedure time and recovery periods by several months. This is of significant interest to patients and clinicians, due to potential improvements in efficiency and efficacy of dental procedures. In July 2022, the Company executed a global exclusive licence and distribution agreement with BioHorizons Implant Systems Inc (**BioHorizons**), one of the largest dental implant companies, for its Striate+ premium dental membrane.

BioHorizon's USA update

Striate+™ continues to impress with momentum building and global market expansion underway

BioHorizons completed a US product launch of Striate+ in November 2022, with a focus on supplying existing Key Opinion Leader (KOL) accounts and other major customers. Since market launch, the BioHorizons marketing and sales team has actively promoted Striate+ at key industry conferences and various educational meetings and workshops. These activities have resulted in a ramp up of product sales and growing revenue in US, Europe, UK and Australia.

Orthocell continues to work with BioHorizons to gain market access in additional large or strategic markets where they have established accounts and/or distribution networks. During the quarter:

1. **BioHorizons continued its sales roll out plan in the key markets of Germany, Austria and Switzerland** following the official launch and first sales of Striate+™ in the previous quarter**;**
2. **BioHorizons executed numerous US focussed education and promotional activities** including a series of guided bone regeneration webinar's, scientific symposia and targeted user group meetings;
3. **Orthocell's regulatory team progressed its global market expansion program** with approval in the strategic market of Brazil and continues to work with BioHorizons to expand approvals in further international jurisdictions; and
4. **A new peer-reviewed study published in BMC Oral Health** providing compelling evidence of the superiority of Orthocell's Striate+™ collagen dental membrane to promote good bone formation and to prevent unwanted epithelial infiltration in a canine model of guided bone regeneration procedures. This research provides valuable scientific validation of Striate+'s performance characteristics and supports its continued development as an advanced solution for guided bone regeneration procedures. Read the journal article: https://bit.ly/OCC_BMC-OralHealth

Remplir™ for nerve regeneration

Remplir is a collagen nerve wrap used in the repair of peripheral nerve injuries. It provides compression-free protection to the nerve, generating an ideal microenvironment to aid nerve healing. Remplir has proven to be an important step forward in the improvement of nerve repair surgery. Its ease of use, consistent and predictable high-quality outcomes will empower surgeons to improve the lives of people navigating these complex injuries. The Company appointed Device Technologies (DVT) as the exclusive distributor of Remplir across Australia and New Zealand in September 2022 and DVT Asia as exclusive distributor in Singapore in November 2024. Remplir is now being sold in Singapore, Australia and New Zealand, where sales continue to grow with an increasing number of surgeons using and endorsing its unique repair qualities.

Device Technologies – Australia and New Zealand update

Remplir™ accounts expanding and momentum building

DVT officially launched Remplir in Australia in November 2022, with a focus on supplying existing orthopaedic and plastic reconstructive KOL accounts. The ramp up of product sold since market launch is gaining traction with >200 orthopaedic and plastic surgeons now using Remplir in peripheral nerve repair surgeries, from facial nerves to upper and lower limb nerves, across Australia and New Zealand. Feedback from the clinicians and DVT salesforce continues to be excellent, with adoption driven by Remplir's unique qualities that enable less suturing, creation of the optimal healing microenvironment and facilitation of free gliding within the repair site during the critical healing period.

During the quarter Orthocell's successfully completed the third Annual Nerve Transfer and Reconstruction Symposium, bringing together leading nerve repair specialists from Australia, the Asia-Pacific region, and around the world to advance knowledge and techniques in nerve repair. The internationally regarded faculty included Dr Ian Valerio's keynote on military trauma applications, opening new conversations about Remplir's potential in complex reconstruction cases. Presentations were also delivered by Dr Natasha Van Zyl, Dr Alex O'Beirne, Dr Tanya Burgess, Dr Vaikunthan Rajaratnam, Dr Sharon Chu and Prof Minghao Zheng.

During Dr Ian Valerio's visit to Australia last week, he also spoke with Stockhead's Tylah Tully to about the significant global opportunity for Remplir, following recent FDA approval. He noted that the technology's proven track record in Australia positions it well for expansion into other markets, with potential to establish Orthocell as a market leader in nerve repair and regenerative surgery globally. Take a look: Click Here

Device Technologies Asia - Singapore update

Key account expansion continues

Orthocell continues to work with DVT Asia to establish key accounts with leading plastic, reconstructive and orthopaedic specialists. Notably, internationally regarded peripheral nerve repair specialist, Dr Vaikunthan Rajaratnam completed a surgical procedure in Singapore using Remplir, which was subsequently published as a high quality white paper and distributed widely to key surgeons in Singapore and globally.

Remplir US launch activities

Well placed to generate first sales with first product use complete

The Company is now cleared to commence commercial distribution into the globally significant US$1.6 billion[1] nerve repair market. Orthocell is well placed to generate first US sales with a US logistics and customer service partner in place, sales pathways already established and significant Remplir™ inventory built up. During the quarter the US based sales, education and marketing team rapidly progressed the sales roll out activities including:

1. **First use of Remplir in the US**. A crucial step in the rollout of Remplir in the significant US market, building surgical experience and knowledge of the product that will be key in driving product sales.
2. **Rapidly established a growing US distributor network of 14 specialist nerve distributors** with mature, direct-to-surgeon, hospital and other customer relationships across 25 US states.
3. **Successfully completed another study** demonstrating that nerve repair with Remplir results in superior regeneration of nerve tissue and earlier return of muscle function, compared to current standard of care, which involves suture-only repair
4. **Clinical presentations and Key Opinion Leader engagements** at the Global Nerve Foundation Brachial Plexus Meeting in NYC together with NYU Langone Health and the Hospital for Special Services (HSS). The strategic event was attended by globally leading PRN surgeons meeting to share advances in the field of peripheral nerve repair.

5. **Scientific research and clinician meetings** at Washington University St Luis, Duke University in North Carolina, Brown University in Rhode Island, Harvard University Massachusetts and Mass General Brigham Hospital led by Orthocell's CSO, Professor Minghao Zheng and Australian PRN specialist Dr Richard Carey-Smith.

Advanced Cellular Therapies

Orthocell's cell therapies aim to treat diseased or damaged tissue by local implantation or injection of healthy cells where tissue repair is needed. The process involves harvesting a piece of healthy tissue (tendon or cartilage) from the patient. The tissue sample is sent to Orthocell's manufacturing facility where the cells are extracted and grown in culture over a few weeks until there are sufficient cell numbers to implant. Characterisation of the final product is performed to assess the cell's purity, potency and identity before implantation, ensuring high quality tissue repair. The use of a patient's own cells to repair tissue damage reduces the risk of rejection or transmission of infectious diseases. Orthocell is licensed by the TGA to manufacture autologous chondrocytes (OrthoACI™) and tenocytes (OrthoATI™) for cartilage and tendon repair.

During the quarter, the Company continued supply of the cellular therapies in the Australian market and remains committed to securing a strategic partner to commercialise OrthoATI in the US without the need for significant investment.

Release authorised by:
Paul Anderson
Orthocell Ltd CEO and MD

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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 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 14 US distributors, with first sales expected to follow shortly. The Company's flagship nerve repair product is also approved in Australia, New Zealand and Singapore and is distributed exclusively by Device Technologies Group. 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 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.

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 June 2025

Consolidated statement of cash flows		**Current quarter $A'000s**	**Year to date (12 months) $A'000s**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	1,337	5,148
1.2	Payments for:		
	(a) research & development (including allocated staff costs)	(827)	(4,842)
	(b) product manufacturing and operating overheads	(1,454)	(4,104)
	(c) marketing, business development & investor relations	(1,376)	(3,323)
	(d) leased assets	(1)	(3)
	(e) staff costs (other than R&D staff)	(1,041)	(3,625)
	(f) administration & corporate costs	(693)	(2,436)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	523	1,475
1.5	Interest & other costs of finance paid	(9)	(14)
1.6	Income taxes paid	-	-
1.7	Government grants & tax incentives received	-	30
1.8	Other (R&D tax incentive rebate)	-	3,185
1.9	**Net cash from / (used in) operating activities**	**(3,541)**	**(8,509)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant & equipment	(60)	(358)
	(d) investments	-	-
	(e) intellectual property	(89)	(139)
	(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**	**(149)**	**(497)**

Consolidated statement of cash flows		Current quarter $A'000s	Year to date (12 months) $A'000s
3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	17,000
		-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of share options	649	1,146
3.4	Transaction costs related to issues of equity securities, or convertible notes	-	(850)
		-	
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)	(58)	(250)
3.10	**Net cash from / (used in) financing activities**	**591**	**17,046**

4.	**Net increase / (decrease) in cash & cash equivalents for the period**		
4.1	Cash & cash equivalents at beginning of period	31,719	20,614
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,541)	(8,509)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(149)	(497)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	591	17,046
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash & cash equivalents at end of period**	**28,620**	**28,654**

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	2,120	3,719
5.2	Term deposits	26,500	28,000
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)**	**28,620**	**31,719**

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	294
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** *Note: the term 'facilty' includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the position.*	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 facilites 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)	(3,541)
8.2	Cash and cash equivalents at quarter end (item 4.6)	28,654
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	28,654
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**8.09**

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:

1. 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

2. 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

3. 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 : 9 July 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.