

ASX Release

23 October 2026

APPENDIX 4C: QUARTER ENDED 30 SEPTEMBER 2026**Highlights for the quarter:**

- Reached clinical readiness, with the first two batches successfully manufactured and released for patient use during September 2026.
- First-in-human clinical trial start-up activities were completed with two sites now active and screening patients; first patient dosing expected this month.
- In vivo studies for Arovella's armoured CLDN18.2-directed CAR-iNKT program, ALA-105, progressing well, with results expected in weeks.
- End of quarter cash of \$11.6 million, with net operating cash outflows of \$2.7 million for the quarter.
- In October, Arovella received its FY26 R&D tax incentive rebate of \$4.03 million, resulting in a pro-forma cash balance of approximately \$15.63 million at the end of the quarter.

During the quarter, Arovella made substantial progress towards commencing clinical evaluation of ALA-101, its lead allogeneic CD19-targeting CAR-iNKT cell therapy. Importantly, it released two batches of ALA-101 for clinical use, activated the first two clinical trial sites and commenced screening patients. ALA-101 is being tested in patients with relapsed or refractory CD19-positive non-Hodgkin lymphoma and certain leukaemias.

Arovella finished the quarter with \$11.6 million in cash. The Company's clear priority remains to obtain preliminary clinical safety and efficacy data for ALA-101 in blood cancers and advance its solid tumour program, ALA-105, towards the clinic. At the same time, the Company expects to unlock significant value from its strategy for autoimmunity by leveraging the clinical data obtained for ALA-101 in blood cancers.

Scalable off-the-shelf manufacturing addresses a recognised CAR-T bottleneck

Manufacturing remains a recognised bottleneck for conventional autologous CAR-T therapies, which require a separate product to be made from each patient's own cells. This complex and individualised process contributes to the high cost of treatment, creates manufacturing and logistical challenges and can leave patients waiting for treatment.

Arovella's approach addresses this challenge by manufacturing ALA-101 from healthy donor-derived invariant natural killer T (iNKT) cells. Its scalable Good Manufacturing Practice (GMP) process enables multiple treatment doses to be produced in advance and stored as off-the-shelf clinical supply. This removes the need to wait for patient-specific manufacturing. Treatment can proceed once screening and other clinical requirements are met. This approach has the potential to remove the need for patient specific manufacturing, simplify treatment logistics and broaden access for patients.

During the quarter Arovella released two clinical batches of the ALA-101 drug product. This provides evidence that the manufacturing process can reproducibly generate clinical supplies. The two batches provide sufficient material to complete dose escalation and begin dose expansion.

Site activation and commencement of screening activities

During the quarter, Arovella activated The Alfred and Epworth Hospital clinical trial sites and commenced screening patients. The Company expects to dose the first patient in October. Dosing is a major milestone for ALA-101, enabling the first assessment of its safety and biological activity in patients.

ALA-101-001 is Arovella's first-in-human trial evaluating ALA-101 in patients with relapsed or refractory CD19-positive non-Hodgkin lymphoma and certain leukaemias. The dose-escalation and expansion study is designed to assess safety and tolerability, determine an appropriate dose for further development, and generate preliminary evidence of anti-tumour activity. Arovella also expects the study to provide important clinical data on ALA-101's expansion, persistence and ability to deplete CD19-positive B cells. This will indicate if it can be applied in blood cancers and autoimmune disease.

As this is the first time ALA-101 has been tested in humans, regulators require us to wait 28 days between dosing patients for the first three patients, and then for the first patient each time we increase the dose, to observe any adverse safety signals. However, screening for new patients can occur during this window so that patients are ready to dose once these observation periods are complete.

By end Q1 CY27, the Company expects to have completed dosing for the first dose level, to have started dosing at the second dose level, and to be enrolling at a faster pace. Since the product is ready 'off-the-shelf', there is no need to wait for manufacturing slots like in a traditional cell therapy trial, which avoids the significant delays that can be caused by needing to schedule these slots. Early patient data are expected to generate key safety and tolerability information as well as initial measures of biological activity such as ALA-101 expansion and persistence, CD19-positive B cell depletion, and preliminary antitumour responses. Arovella is currently activating two more clinical trial sites to support recruitment, with more sites becoming active once initial safety data is available.

In vivo animal models for ALA-105 progressing well

In vivo animal studies evaluating Arovella's armoured CLDN18.2-targeting CAR-iNKT cells are progressing well, with data expected in the coming weeks. These results will provide important evidence of the program's anti-tumour activity in solid tumour models and, if supportive, will inform and support the continued advancement of ALA-105 towards the clinic. Solid tumours represent a significant unmet need and a large commercial opportunity, with conventional CAR-T therapies yet to demonstrate the transformative efficacy achieved in blood cancers. Arovella believes its CAR-iNKT cells may be better able to reach and attack cancer cells in the difficult tumour environment and provide meaningful differentiation from conventional CAR-T approaches.

FINANCIAL UPDATE

Arovella is in a strong financial position, with \$11.6 million in cash and cash equivalents as at 30 September 2026. Net cash outflows from operating activities during the quarter were \$2.7 million and the research and development and staff costs for the quarter represented 89% of the Company's operating outflows.

The Company also announced on 22 October 2026 its FY26 R&D tax incentive rebate amount of \$4.03 million. On a pro-forma basis, adding the refund to Arovella's reported cash balance of \$11.6 million at 30 September

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2026 results in a cash position of approximately \$15.63 million, before cash movements since 30 September 2026.

PAYMENTS TO RELATED PARTIES

In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in item 6.1 of Appendix 4C comprise directors' fees, salaries and superannuation. Payments made for the quarter total \$57,500 for payments to the Non-Executive Directors.

OUTLOOK FOR CY26

The Company enters the final quarter of 2026 with a strong focus and momentum across both its clinical and preclinical programs. Key near-term milestones include:

- Dosing the first patient in the ALA-101 first-in-human clinical trial for blood cancers
- Completion of in vivo efficacy studies evaluating armoured CAR-iNKT cells in animal models as part of the solid tumour program.
- Generation of initial clinical data from ALA-101, including the potential for ALA-101 to deplete CD19-positive B cells to support expansion to autoimmune disease.
- Preparation and submission of regulatory filings to support the expansion of ALA-101 into autoimmune disease.
- Commencement of IND-enabling non-clinical and manufacturing activities for ALA-105

Arovella believes the forthcoming ALA-101 clinical data have the potential to demonstrate the promise of the CAR-iNKT platform, and to support expansion into solid tumours and autoimmune disease indications. This would position the Company as a leader in next-generation allogeneic cell therapy development and significantly improve patient access and speed to treatment.

INVESTOR WEBINAR

On 12 August, Arovella held an investor webinar, where the Company shared an update following the Board's recent strategic review and our progress toward the phase 1 first-in-human trial of ALA-101.

The webinar was hosted by Bell Potter and presented by Arovella Chair, David Williams and Acting CEO, Dr Nicole van der Weerden.



[View webinar recording and slides](#)

CELL AND GENE MEETING ON THE MESA

From 5-7 October, Acting CEO Dr Nicole van der Weerden and Senior VP Manufacturing & Quality Dr Robson Dossa attended Cell and Gene Meeting on the Mesa in Phoenix, Arizona. The meeting is the leading annual conference for the cell and gene therapy sector, bringing together senior executives and industry leaders to advance the development of innovative therapies.

Dr van der Weerden delivered a presentation as part of the Innovation Spotlight program which highlights the latest scientific, clinical, manufacturing, regulatory and commercial advancements from organisations across the advanced therapies ecosystem. Dr van der Weerden and Dr Dossa also attended over 30 one-on-one face-to-face meetings with potential investors, pharma companies, partners, and suppliers.

[View the presentation](#)



INVESTOR RELATIONS



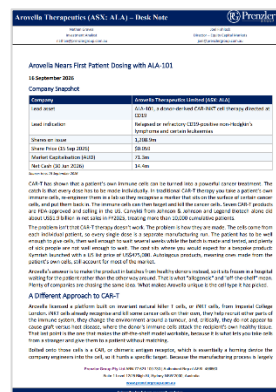
Bioshares Biotech Summit

From 5-7 August, Acting CEO Dr Nicole van der Weerden and Chair David Williams attended the 20th Bioshares Biotech Summit in Queenstown, New Zealand. They enjoyed exchanging insights, sharing learnings, and engaging with industry peers and investors throughout the event.

Chair David Williams also delivered the Mike Hirshorn keynote address.

Prenzler Analyst Coverage

In September, Prenzler Group wrote a desk note on Arovella. The report provides an overview of Arovella's progress and outlines why the upcoming first patient dosing study represents a significant milestone for the Company.

[View Prenzler desk note](#)

INDUSTRY NEWS

The following pages summarise some recent developments in the cell therapy sector and explain their relevance to Arovella and its development programs.

CAR-iNKT FDA regulatory development

Highlights:

- **BrightPath announced US FDA IND clearance to the Tokyo Stock Exchange for its investigational CAR-iNKT therapy, permitting a first-in-human trial**
- **Both Arovella and BrightPath are developing off-the-shelf CAR-iNKT therapies, differentiated from conventional patient-specific CAR-T therapies**
- **Arovella uses healthy donor-derived iNKT cells, BrightPath uses iPSC-derived iNKT cells**
- **Arovella's donor-derived iNKT cells have undergone natural development in the immune system, which is expected to make them better at killing tumour cells than iPSC-derived iNKT cells that have been reprogrammed in laboratory conditions**

The US Food and Drug Administration (FDA) clearance announced by BrightPath Biotherapeutics (TSE: 4594) (BrightPath) on 3 August 2026 is highly relevant to Arovella Therapeutics (ASX: ALA). [View BrightPath announcement.](#)

The clearance of BrightPath's Investigational New Drug (IND) application permits a first-in-human study in patients with relapsed or refractory multiple myeloma. BrightPath has an off-the-shelf CAR-iNKT therapy made from induced pluripotent stem cells (iPSCs). BrightPath stated that it was working to open US clinical sites with the intention of commencing patient dosing later in 2026.

Arovella considers this development highly relevant to investors as it supports continued development of the broader CAR-iNKT field. Arovella's use of healthy donor-derived iNKT cells is expected to offer a potency advantage over Brightpath's iPSC-derived product because the cells are sourced directly from naturally occurring, functionally mature iNKT cells rather than generated through reprogramming and differentiation. This natural immune development is expected to make the cells more potent and better at killing tumour cells than iPSC-derived iNKT cells.

Arovella's therapeutic targets are also distinct from BrightPath's, further differentiating the Company's development programs. Arovella is targeting CD19 for lymphomas, leukaemias and autoimmunity and claudin 18.2 for solid tumours while Brightpath is targeting BCMA for multiple myeloma.

Arovella's donor-derived products have the potential to be delivered to patients faster and at a lower cost than cell therapies derived from a patient's own blood. The platform also has other benefits, including potential for a superior safety profile (i.e. lower risk of an adverse patient response) and greater ability to infiltrate tumours. In addition to its engineered CD19 CAR, ALA-101 retains natural iNKT recognition pathways, including recognition of glycolipid antigens presented by CD1d through the invariant T-cell receptor, and recognition of stress ligands through NKG2D. These biological properties underpin Arovella's development rationale. Potential advantages in tumour targeting, safety, access and cost remain subject to clinical evaluation and manufacturing and economic validation.

Recent clinical data strengthen the case for allogeneic cell therapy in autoimmune disease

Highlights:

- **Adicet Bio announced encouraging results for an allogeneic cell therapy in autoimmune disease**
- **Provides clinical evidence that an allogeneic, donor-derived B cell-targeting CAR cell therapy can generate durable clinical activity in autoimmune disease after a single treatment**

Recent results from Adicet Bio announced on 28 September 2026 provide encouraging clinical validation for the potential use of off-the-shelf, allogeneic cell therapies in autoimmune disease. [View Adicet Bio announcement.](#)

In its phase 1 study of prula-cel, an allogeneic CD20-directed gamma-delta CAR-T therapy, Adicet Bio reported that 54% of evaluable lupus patients achieved DORIS remission at 12 months, while 50% of evaluable patients with lupus nephritis achieved a complete renal response. All patients discontinued immunosuppressants and all but one reduced corticosteroids to ≤ 5 mg prednisone equivalent per day. Responses observed at 12 months were reported as generally maintained through 12–21 months of follow-up.

Importantly, all 22 efficacy-evaluable patients achieved profound B-cell depletion followed by naïve-dominant B-cell reconstitution, consistent with the concept of an immune reset.

The significance for Arovella is the broader biological read-through: these results provide clinical evidence that an allogeneic, donor-derived B cell-targeting CAR cell therapy can generate durable clinical activity in autoimmune disease after a single treatment, challenging the view that prolonged persistence of an autologous CAR-T product is necessarily required to achieve lasting benefit.

This is highly relevant to ALA-101, Arovella's allogeneic CAR-iNKT platform. While ALA-101 is a different cell type and targets CD19 rather than CD20, the Adicet Bio prula-cel study supports the underlying hypothesis that sufficiently deep depletion of pathogenic B cells may permit immune reconstitution and sustained clinical benefit without requiring a patient-specific cell product. For Arovella, this provides encouraging external clinical validation of the rationale for investigating an off-the-shelf approach to autoimmune disease.

Autoimmune CAR-T safety events highlight the potential importance of ALA-101's differentiated cell type

Highlights:

- **Serious inflammatory safety events in conventional autologous CAR-T autoimmune trials underscore the need for therapies with a safety profile suited to patients with chronic autoimmune disease.**
- **If ALA-101 demonstrates the expected favourable safety profile of its allogeneic CAR-iNKT platform, it could provide important differentiation in autoimmune disease while retaining the benefits of deep B cell depletion and off-the-shelf availability.**

Recent developments in autoimmune CAR-T reinforce that safety is likely to be a critical determinant of which cell therapies can ultimately succeed in autoimmune disease, creating an opportunity for Arovella Therapeutics to differentiate ALA-101 if the favourable safety characteristics anticipated from its CAR-iNKT platform translate clinically.

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As published in [Fierce Biotech](#) on 31 August 2026, Novartis temporarily halted eight autoimmune and neurological studies of its autologous CD19 CAR-T rapcabtagene autoleucel (rap-cel) following three serious cases of immune effector cell-associated haemophagocytic syndrome (IEC-HS) with fatal outcomes. Bristol Myers Squibb separately paused enrolment in autoimmune studies of its CD19 CAR-T zola-cel following what the company described as transient and reversible inflammatory events.

These developments do not diminish the compelling evidence that deep B cell depletion can produce meaningful and durable responses in autoimmune disease. Rather, in our view, they highlight an increasingly important challenge for the field: delivering the efficacy associated with CAR-based B cell depletion with a safety profile appropriate for patients with chronic autoimmune diseases. The risk-benefit threshold in autoimmune disease is likely to be different from that in heavily pre-treated patients with life-threatening malignancies.

This creates a potentially important opportunity for ALA-101. Unlike the autologous conventional T cell products involved in the recent trial pauses, ALA-101 is an allogeneic CD19-targeting CAR-iNKT cell therapy. Arovella Therapeutics is currently advancing ALA-101 into its first-in-human phase 1 study in relapsed or refractory CD19-positive blood cancers, with the study explicitly designed to evaluate safety and tolerability alongside preliminary anti-tumour activity and B cell depletion.

If ALA-101 demonstrates a favourable clinical safety profile, we believe this could become an important point of differentiation as Arovella considers expansion into autoimmune disease. Combined with emerging evidence from other developers that durable autoimmune remissions can be achieved using allogeneic cell therapy (see previous page), the recent safety events reinforce the rationale for developing alternative immune-cell platforms capable of achieving profound B cell depletion without the inflammatory toxicity observed with some conventional CAR-T approaches.

For Arovella, this creates a clear development opportunity: to establish ALA-101 first as a clinically safe and active allogeneic CAR-iNKT therapy and, if supported by the data, leverage those characteristics into autoimmune diseases where safety, accessibility and an off-the-shelf treatment model could be particularly valuable.

Release authorised by Arovella Limited Board of Directors.

FURTHER INFORMATION

Dr Nicole van der Weerden

Acting Chief Executive Officer

E nvanderweerden@arovella.com

M +61 407 039 983

David Williams

Chairman

E dwilliams@kidder.com.au

M + 61 414 383 594

About Arovella Therapeutics Ltd

Arovella Therapeutics Ltd (ASX: ALA) is focused on developing its invariant natural killer T (iNKT) cell therapy platform licensed from Imperial College London to treat blood cancers, solid tumours, and autoimmune disease. Arovella's lead product is ALA-101. ALA-101 consists of CAR19-iNKT cells that have been modified to produce a

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Chimeric Antigen Receptor (CAR) that targets CD19. CD19 is an antigen found on the surface of numerous cancer types. iNKT cells also contain an invariant T cell receptor (iTCR) that targets glycolipid bound CD1d, another antigen found on the surface of several cancer types. ALA-101 has had its Investigational New Drug application (IND) accepted by the US FDA and is being developed as an allogeneic cell therapy, which means it can be given from a healthy donor to a patient. Arovella is also expanding into solid tumour treatment through its CLDN18.2-targeting technology licensed from Sparx Group. Arovella will also incorporate its IL-12-TM technology into its solid tumour programs.

Glossary: **iNKT cell** – invariant Natural Killer T cells; **CAR** – Chimeric Antigen Receptor that can be introduced into immune cells to target cancer cells; **TCR** – T cell receptors are a group of proteins found on immune cells that recognise fragments of antigens as peptides bound to MHC complexes; **B-cell lymphoma** – A type of cancer that forms in B cells (a type of immune system cell); **CD1d** – Cluster of differentiation 1, which is expressed on some immune cells and cancer cells; **aGalCer** – alpha-galactosylceramide is a specific ligand for human and mouse natural killer T cells. It is a synthetic glycolipid.

For more information, visit www.arovella.com

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

Arovella Therapeutics Limited

ABN

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Quarter ended ("current quarter")

30 September 2026

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers		
1.2	Payments for		
	(a) research and development	(1,720)	(1,720)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(825)	(825)
	(f) administration and corporate costs	(304)	(304)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	143	143
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (GST)	(26)	(26)
1.9	Net cash from / (used in) operating activities	(2,732)	(2,732)
2.	Cash flows from investing activities		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and 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 (Security deposits)	-	-
2.6	Net cash from / (used in) investing activities	-	-

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 options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other	-	-
3.10	Net cash from / (used in) financing activities	-	-

4.	Net increase / (decrease) in cash and cash equivalents for the period		
		14,353	14,353
4.1	Cash and cash equivalents at beginning of period		
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,732)	(2,732)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	(19)	(19)
4.6	Cash and cash equivalents at end of period	11,602	11,602

5.	Reconciliation of cash and 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'000	Previous quarter \$A'000
5.1	Bank balances	1,537	1,614
5.2	Call deposits	10,065	12,739
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	11,602	14,353

6.	Payments to related parties of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	58
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>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.</i>		
The amount at 6.1 includes Director fees for Non-Executive Directors (including superannuation).		

7.	Financing facilities <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
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, maturity date and whether it is secured or unsecured. If any additional financing 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'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(2,732)
8.2	Cash and cash equivalents at quarter end (item 4.6)	11,602
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	11,602
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	4.2
<i>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.</i>		
8.6	If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1	Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
	Answer: N/A	
8.6.2	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	
8.6.3	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	
<i>Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.</i>		

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: 23/10/2026.....

Board of Directors

Authorised by:
(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.