

ASX: ALA

Arovella Therapeutics Limited
ACN 090 987 250



ASX Release

30 October 2025

APPENDIX 4C: FIRST QUARTER FY26

Highlights for the quarter:

- Cash and cash equivalents at 30 September of \$21.9 million
- Progressed preparation of Investigational New Drug (IND) application for ALA-101
- Held Type D meeting with FDA to de-risk IND application for ALA-101
- CRO selected for first-in-human phase 1 trial for ALA-101
- Received Notice of Allowance for US patent application covering core platform intellectual property
- Demonstrated potent activity of new CLDN18.2-targeting CAR for ALA-105 program
- Received \$3.2 million R&D tax incentive rebate
- Key milestones expected in CY25 for ALA-101 include GMP manufacturing and IND submission in readiness for the start of a phase 1 clinical trial in early CY26.

MELBOURNE, AUSTRALIA 30 October 2025: Arovella Therapeutics Limited (ASX: ALA) (**Arovella** or the **Company**), a biotechnology company focused on developing its invariant Natural Killer T (iNKT) cell therapy platform, today releases its Appendix 4C for the first quarter of FY26.

Arovella continues to progress its lead product, ALA-101, towards a first-in-human clinical trial and to expand its platform into solid tumours. The Company finished the fourth quarter with cash of \$21.9 million, which is expected to fund the Company through to the completion of patient enrolment for the phase 1 clinical trial for ALA-101. The funding will also support the advancement of the Company's solid tumour programs (CLDN18.2-CAR-iNKT targeting gastric cancer) and its armouring program (IL-12-TM).

Arovella's CEO and MD, Dr Michael Baker, remarked, "It was a productive quarter at Arovella. We made significant progress preparing our IND application and held a successful Type D meeting with FDA which provided valuable feedback on the data required to support that application. Our clinical trial preparatory activities for ALA-101 are increasing as we work towards dosing patients in early 2026, and we are delighted to be working with SAPRO as our CRO for the study. We remain enthusiastic about our expanding pipeline targeting solid tumours, including ALA-105, which employs a CAR that recognises the clinically-validated target, CLDN18.2, as well as the potential for additional CARs targeting GD2 and GPC3 which remain under Option from Baylor College of Medicine. The data we obtain from our first-in-human trial for ALA-101 informs not only the development of ALA-101, but also directly translates to Arovella's solid tumour programs.

IND PROGRESS AND TYPE D MEETING UPDATE

During the quarter, Arovella made excellent progress towards submitting an IND application with FDA for ALA-101. This involved holding a Type D meeting with FDA to align on the testing requirements for a key cGMP reagent. The outcome of this Type D meeting was positive, and the agency provided clear guidance on expectations for the testing requirements. Arovella has already completed much of the testing required and is now working to obtain the additional data requested by FDA. The Company expects to file its IND application before the end of CY25.

TAKING ALA-101 INTO A FIRST-IN-HUMAN PHASE 1 CLINICAL TRIAL

While progressing its IND application, Arovella has also continued planning for its phase 1 first-in-human study for ALA-101. The phase 1 study is an open-label, dose escalation and dose expansion trial targeting CD19-positive non-Hodgkin's lymphoma and leukemia with initial clinical sites anticipated to be located across Australia and New Zealand. The initial dose escalation part of the trial will assess the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary efficacy of a single dose of ALA-101 and establish the maximum tolerated dose (MTD) for the expansion phase. A Bayesian design will be employed to enable efficient dose escalation and to maximise the likelihood that patients are enrolled at a safe and effective dose. The dose expansion part of the trial will further characterise the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy of ALA-101. The commencement of the trial is subject to human research ethics committee (HREC) approval and local institutional approvals.

In October, Arovella announced the appointment of SAPRO as its clinical research organisation (CRO) partner for the trial. SAPRO was selected after an extensive and rigorous selection process conducted by the Arovella management team. Arovella anticipates the dose escalation part of the trial to commence in early CY26.

UPDATE ON NON-EXECUTIVE CHAIR

On 1 July 2025, Dr Thomas Duthy retired as a Non-Executive Director and Chair of the Company to pursue new business opportunities. Dr Duthy was Chairman of Arovella since March 2023.

Dr Elizabeth Stoner, one of Arovella's Non-Executive Directors, is currently serving as interim Chair while the Company undertakes a thorough global process to appoint a new Chair. The process identified multiple highly credentialed individuals to join the Arovella Board of Directors. The preferred candidate has been selected, and the final details are being negotiated. The candidate has an exceptional background, previously at a high-profile Australian life sciences and pharmaceutical company, and the individual is well versed in the scientific and commercial aspects of drug development. The candidate will join as non-Executive director, before making the anticipated transition to chair, and an appointment is expected to be announced this quarter.

ALA-105, A SOLID TUMOUR PRODUCT TARGETING CLAUDIN 18.2

During the quarter, research conducted by Arovella at the University of North Carolina, under the guidance of Professor Gianpietro Dotti, further confirmed the functionality of its novel claudin 18.2 (CLDN18.2)-targeting chimeric antigen receptor (CAR) by demonstrating that CLDN18.2 CAR-T cells robustly eliminate pancreatic cancer cells that express CLDN18.2 *in vitro*. The study confirmed the potent activity of Arovella's CLDN18.2 CAR against a pancreatic cancer cell line, with pancreatic cancer being one of the more aggressive, and low survival cancer types with limited treatment options.

The human pancreatic adenocarcinoma cell line, PaTu8988S, naturally expresses CLDN18.2 and was selected as a model cell line for this study. Arovella's novel CAR design is based on the patent protected CLDN18.2 antigen-binding sequences of the SPX-101 monoclonal antibody, for which Arovella has an exclusive license for use in cell therapies. CLDN18.2 CAR-T cells generated from three independent donors were cultured *in vitro* with twice the number of PaTu8988S cells for 3 days, and then the degree of cytotoxicity was measured. The results demonstrated that CAR-T cells expressing Arovella's CLDN18.2 CAR displayed robust killing of pancreatic cancer

cells (Figure 1), and the activity was similar to that observed for a control CAR generated based upon the CARsgen Therapeutics CT041 CAR. CARsgen Therapeutics recently filed a New Drug Application (NDA) for its autologous CLDN18.2 CAR-T cell product which has been accepted for review by the Chinese regulator, the National Medical Products Administration (NMPA)¹. The NDA was based on results from an open-label, multicentre, randomised controlled confirmatory Phase II clinical trial (CT041-ST-01, NCT04581473) conducted in China.

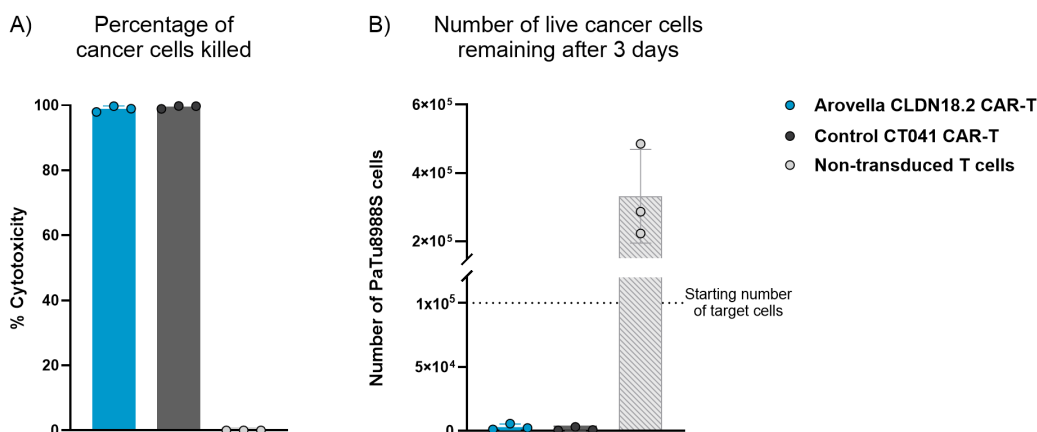


Figure 1. Cytotoxicity of CAR-T cells expressing Arovella's CLDN18.2-targeting CAR against the human pancreatic adenocarcinoma cell line, PaTu8988S. CAR-T cells were cultured with PaTu8988S cells at an effector-to-target ratio of 1:2 for 3 days and then analysed by flow cytometry. (A) Percentage cytotoxicity calculated relative to PaTu8988S target cells cultured with non-transduced T cells, (B) Number of live PaTu8988S target cells remaining following the co-culture with CAR-T cells or non-transduced T cells. Data is presented for three donors $\pm$ Standard Error of Mean (SEM).

Importantly, recent publications have demonstrated that CAR-iNKT cells outperform CAR-T cells in fighting solid tumours by shaping the tumour microenvironment (TME) and promoting the cross-priming of other cytotoxic immune cells to eliminate the cancer cells^{2,3}. It is anticipated that Arovella's CLDN18.2-CAR-iNKT cells will perform better than CAR-T cells due to their additional functionality within the TME. The next steps for the program are to engineer iNKT cells to express the CLDN18.2 CAR, test the activity of these cells against CLDN18.2 positive cell lines, and commence *in vivo* pancreatic and gastric cancer studies in mice.

US PATENT FOR AROVELLA CAR-iNKT CELL PLATFORM TO PROCEED TO GRANT

On 15 August 2025, the United States Patent and Trademark Office issued a Notice of Allowance indicating their intention to grant a patent from US patent application no. 16/977,346 directed to Arovella's iNKT cell therapy platform, which is under licence to Arovella from Imperial College Innovations Limited.

The patent application, which covers the manufacturing of CAR-iNKT cells, is expected to proceed to grant in 2025 following completion of the grant formalities. Once granted, the patent will have a term of protection to at least 28 February 2039, subject to any patent term adjustment. The US Patent Application No. 16/977,346 is titled "TRANSDUCTION AND EXPANSION OF CELLS".

¹ <https://www.carsgen.com/en/news/20250626/>

² https://www.science.org/doi/10.1126/sciimmunol.abn6563?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

³ <https://www.nature.com/articles/s43018-024-00830-0>

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The allowance of US 16/977,346 accompanies granted patents in Europe, Canada and Hong Kong, an accepted patent application in Australia, and additional corresponding applications, including divisional patent applications, in Canada, China, Europe and Hong Kong.

FINANCIAL UPDATE

During the quarter, Arovella received its FY25 R&D Tax Incentive refund of \$3.2 million. These funds further strengthen Arovella's cash position as it progresses development of its lead asset, ALA-101, towards first-in-human clinical trials. Arovella maintains a strong financial position, with \$21.9 million in cash and cash equivalents as at 30 September 2025.

Cash outflows from operating activities during the quarter was \$2.7 million and the research and development and staff costs for the quarter represented 81% of the Company's operating outflows.

Payments to Related Entities

In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in item 6.1 of Appendix 4C incorporates directors' fees, salaries and superannuation. Payments made for the quarter total \$269,206 and relate to payments to the CEO/Managing Director in accordance with employment contracts and payments to the Non-Executive Directors.

OUTLOOK FOR FY26

Arovella remains in a strong financial position with a solid balance sheet as it advances its lead program, ALA-101, towards a first-in-human phase 1 clinical trial. The trial is expected to commence early in 2026, and the Company is funded to complete enrolment and report initial safety and efficacy data. Additionally, the Company is making progress with its solid tumour program targeting CLDN18.2 and looks forward to generating data using the CLDN18.2 CAR in iNKT cells, as well as integrating IL-12-TM. The Company continues to review new technologies for acquisition that could enhance the CAR-iNKT cell platform or expand its application to target various cancer types. The company looks forward to providing updates in due course.

INVESTOR RELATIONS AND NEWS

Non-Deal Roadshow



In July, Arovella CEO, Dr Michael Baker, provided an update to investors in the form of a non-deal roadshow in Australia, Singapore and Hong Kong.

[View presentation](#)

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Monsoon AU CAR-T Showcase

On 12 August, Arovella CEO, Dr Michael Baker, spoke at the AU CAR-T Showcase hosted by Monsoon Communications.

[View presentation recording](#)



TechKnow Invest Roadshow

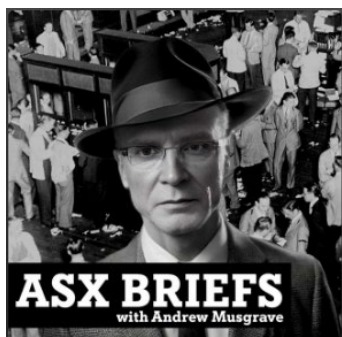
On 19 August in Melbourne and 21 August in Sydney, Dr Michael Baker, presented at the TechKnow Invest Roadshow. Investors also had the opportunity to listen to Dr Michael Baker, Brian Leedman (BlinkLab Limited) and Stuart Roberts (Pitt Street Research) who provided their views on the biotech sector and investing in the space.

[View presentation recording](#)

Dr Michael Baker interview with Stockhead

On 2 September, Stockhead's Tylah Tully chatted with Dr Michael Baker on how the company's soon-to-be-granted US patent for its CAR-iNKT cell therapy platform marks a major milestone in strengthening IP protection in a key global market.

[View full interview](#)



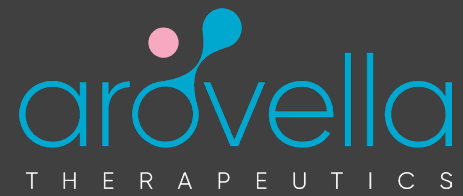
Dr Michael Baker interview with ASX Briefs

On 4 September, Dr Michael Baker was interviewed by Andrew Musgrave and discussed how the company's groundbreaking work with invariant natural killer T-cells (iNKT cells) is transforming cancer treatment through truly off-the-shelf cell therapies.

[Listen to the podcast episode on Spotify](#)

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ALA presents at ASX SMIDCaps Conference

On 24 September, Dr Michael Baker presented at the ASX SMIDCaps conference in Sydney. ASX, in partnership with Bell Financial Group, brings investors up close and personal with emerging companies as they present their vision, strategy and investment proposition.

[View recording of Dr Baker's presentation](#)



Dr Michael Baker presents at AusBiotech Invest

On 21 October, Dr Michael Baker, presented at Australia's premier life science investment conference, AusBiotech Invest. Dr Baker presented Arovella's iNKT cell therapy platform and described how Arovella's technology provides important advantages over existing T-cell therapies and has the potential to be applied to both blood cancers and solid tumours.

[View presentation](#)

This announcement has been authorised for release by the Company's Board of Directors.

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NOTES TO EDITORS:

About Arovella Therapeutics Ltd

Arovella Therapeutics Ltd (ASX: ALA) is a biotechnology company focused on developing its invariant natural killer T (iNKT) cell therapy platform from Imperial College London to treat blood cancers and solid tumours. Arovella's lead product is ALA-101. ALA-101 consists of CAR19-iNKT cells that have been modified to produce a Chimeric Antigen Receptor (CAR) that targets CD19. CD19 is an antigen found on the surface of numerous cancer types. Arovella is also expanding into solid tumour treatment through its CLDN18.2-targeting technology licensed from Sparx Group. iNKT cells also contain an invariant T cell receptor (iTCR) that targets α -GalCer bound CD1d, another antigen found on the surface of several cancer types. ALA-101 is being developed as an allogeneic cell therapy, which means it can be given from a healthy donor to a patient.

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.

For more information, visit www.arovella.com

This announcement contains certain statements which may constitute forward-looking statements or information ("forward-looking statements"), including statements regarding negotiations with third parties and regulatory approvals. These forward-looking statements are based on certain key expectations and assumptions, including assumptions regarding the actions of third parties and financial terms. These factors and assumptions are based upon currently available information, and the forward-looking statements herein speak only of the date hereof. Although the expectations and assumptions reflected in the forward-looking statements are reasonable in the view of the Company's directors and management, reliance should not be placed on such statements as there is no assurance that they will prove correct. This is because forward-looking statements are subject to known and unknown risks, uncertainties and other factors that could influence actual results or events and cause actual results or events to differ materially from those stated, anticipated or implied in the forward-looking statements. These risks include but are not limited to: uncertainties and other factors that are beyond the control of the Company; global economic conditions; the risk associated with foreign currencies; and risk associated with securities market volatility. The Company assumes no obligation to update any forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements, except as required by Australian securities laws and ASX Listing Rules.

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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 2025

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		(1,453)	(1,453)
(b) product manufacturing and operating costs		-	-
(c) advertising and marketing		(36)	(36)
(d) leased assets		-	-
(e) staff costs		(762)	(762)
(f) administration and corporate costs		(479)	(479)
1.3 Dividends received (see note 3)		-	-
1.4 Interest received		245	245
1.5 Interest and other costs of finance paid		-	-
1.6 Income taxes paid		-	-
1.7 Government grants and tax incentives		3,209	3,209
1.8 Other (GST)		107	107
1.9 Net cash from / (used in) operating activities		831	831
2. Cash flows from investing activities			
2.1 Payments to acquire or for:			
(a) entities		-	-
(b) businesses		-	-
(c) property, plant and equipment		(45)	(45)
(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)	(1)	(1)
2.6	Net cash from / (used in) investing activities	(46)	(46)

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	302	302
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(18)	(18)
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	284	284

4.	Net increase / (decrease) in cash and cash equivalents for the period		
		20,877	20,877
4.1	Cash and cash equivalents at beginning of period		
4.2	Net cash from / (used in) operating activities (item 1.9 above)	831	831
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(46)	(46)

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)	284	284
4.5	Effect of movement in exchange rates on cash held	(3)	(3)
4.6	Cash and cash equivalents at end of period	21,943	21,943

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	1,203	612
5.2	Call deposits	20,740	20,265
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)	21,943	20,877

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	269
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 and salary (including superannuation) and short-term incentive for the CEO and Managing Director.		

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)	831
8.2 Cash and cash equivalents at quarter end (item 4.6)	21,943
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	21,943
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	N/A
<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: 30 October 2025
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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.