ASX Release

25 January 2024

APPENDIX 4C: SECOND QUARTER FY 2024

MELBOURNE, AUSTRALIA 25 January 2024: Arovella Therapeutics Ltd (ASX: ALA), a biotechnology company focused on developing its invariant Natural Killer T (iNKT) cell therapy platform for cancer treatment, today releases its Appendix 4C for the second quarter of FY24.

During the quarter, Arovella continued to advance its iNKT cell therapy towards first-in-human clinical trials. Arovella's technology provides key advantages over existing CAR-T cell therapies and has the potential to be applied to both blood cancers and solid tumours.

Arovella is in a solid financial position with pro-forma cash and cash equivalents of $4.76 million as at 31 December 2023.

During the last quarter, Arovella:

- Progressed its solid tumour strategy by signing an exclusive license with Sparx Group to develop a world-first CAR-iNKT cell therapy targeting a validated target, Claudin 18.2 (CLDN18.2), which is expressed in gastric cancers (GC), gastroesophageal junction cancers (GEJC) and pancreatic Cancer (PC);
- Completed GMP manufacturing and release of the ALA-101 lentiviral vector, a key component required for GMP manufacturing of its lead CD-19-targeting iNKT cell product, and continued to advance its manufacturing process development and scale-up activities;
- Received its FY23 R&D Tax Incentive refund of $1.92 million, further strengthening its cash position as it progresses development of its lead asset, ALA-101, towards first-in-human clinical trials; and
- Appointed Tim Luscombe as its new Chief Financial Officer (CFO) and Company Secretary.

Over the coming 12 months, **Arovella** expects to achieve several critical milestones, including:

- Presenting initial proof-of-concept data for its new program, CLDN18.2-iNKT cells (H1 CY24)
- Manufacturing clinical batches of ALA-101 for phase I clinical trials (H1 CY24);
- Completing Investigational New Drug (IND)-enabling non-clinical safety and efficacy studies (H1 CY24);
- Securing an Investigational New Drug (IND) application with the FDA and/or regulatory filing with TGA to conduct a phase I clinical trial in non-Hodgkin's lymphoma (H2 CY24);
- Commence a phase I clinical trial in non-Hodgkin's lymphoma (H2 CY24); and
- In-license additional technologies to enhance the iNKT cell therapy platform.

EXPANDING INTO SOLID TUMOURS

In October, Arovella expanded its pipeline to target solid tumours by signing an exclusive license with Sparx Group to develop a world-first CAR-iNKT cell therapy targeting a validated target, Claudin 18.2.

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Arovella's iNKT cell therapy platform has several advantages over existing CAR-T treatments, particularly for solid tumours. iNKT cells:

- Can be taken from a healthy donor and given to patients without causing graft versus host disease (GvHD);
- Contain an invariant T cell receptor (iTCR) that targets lipid-bound CD1d, present on several tumour types;
- Can be modified to produce a chimeric antigen receptor (CAR) to target specific tumours, making them dual-targeting for tumours that express the target antigen and CD1d;
- Can be expanded >5,000 fold to generate a significant number of doses from a single manufacturing batch;
- Naturally fight solid tumours as shown through the correlation between the natural level of iNKT cells in a cancer patient and improved prognosis in several solid tumour types, including head and neck and colorectal cancer;[1,2]
- Can modify the tumour microenvironment and kill pro-tumour cells such as myeloid-derived suppressor cells (MDSCs) and tumour associated macrophages (TAMs); and
- Can recruit other immune cells to aid in tumour destruction.

Arovella has recently secured a global, exclusive licence for the use of a novel monoclonal antibody (mAb) sequence targeting Claudin 18.2 (CLDN18.2) in cell therapies. The mAb, known as SPX-101, has completed all preclinical proof-of-concept, safety and specificity studies and toxicology studies required to commence a phase 1 trial to treat gastric cancers.

Arovella will use the sequence to develop a world-first CAR-iNKT cell therapy targeting CLDN18.2. CLDN18.2 is a validated target which is expressed in gastric cancers (GC), gastroesophageal junction cancers (GEJC) and pancreatic cancer (PC). Initial proof-of-concept data to demonstrate the potential of this approach is expected to be available in H1 CY24.

CLDN18.2 is a validated target, demonstrated by the fact that there are several products currently in clinical development. The most advanced of these is zolbetuximab, which was acquired by Astellas Pharma during its takeover of Ganymed Pharmaceuticals in 2016 for €422 million up-front and the potential for €860 million in milestones. Zolbetuximab has also been awarded Priority Review for treating GC and GEJC by the FDA, highlighting the high unmet need for patients with these diseases. The FDA's decision to approve zolbetuximab is expected in 2024.

[1] https://ascopubs.org/doi/pdf/10.1200/JCO.2006.08.5787
[2] https://aacrjournals.org/clincancerres/article/11/20/7322/188684/Increased-Intratumor-V-24-Positive-Natural-Killer

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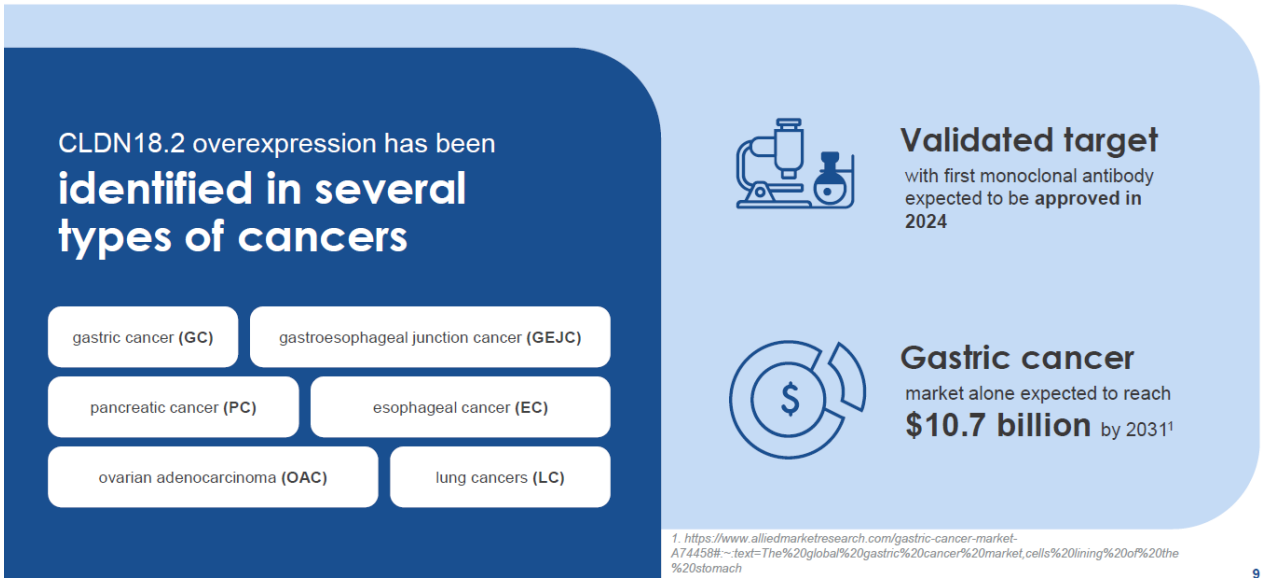

To learn more about the Arovella's CLDN18.2-targeting therapy you can watch the recorded investor webinar available on the Company's website or by clicking the image below.

PROGRESS TOWARDS CLINICAL MANUFACTURING

Arovella is developing ALA-101 to treat CD19+ lymphomas and leukemias. A key requirement for the development of an iNKT cell therapy product is the establishment of the manufacturing process under GMP conditions. A critical component for this manufacturing is the GMP-grade lentiviral vector, which carries the genetic material to reprogram iNKT cells to target and eliminate cancer cells. The vector used to manufacture ALA-101 is a 3rd-generation lentiviral vector manufactured by Lentigen Technology, Inc, a world-leading manufacturer of lentiviral vectors for cell and gene therapies. In December, Arovella completed the manufacture and release testing of the ALA-101 GMP-grade lentiviral vector. It also

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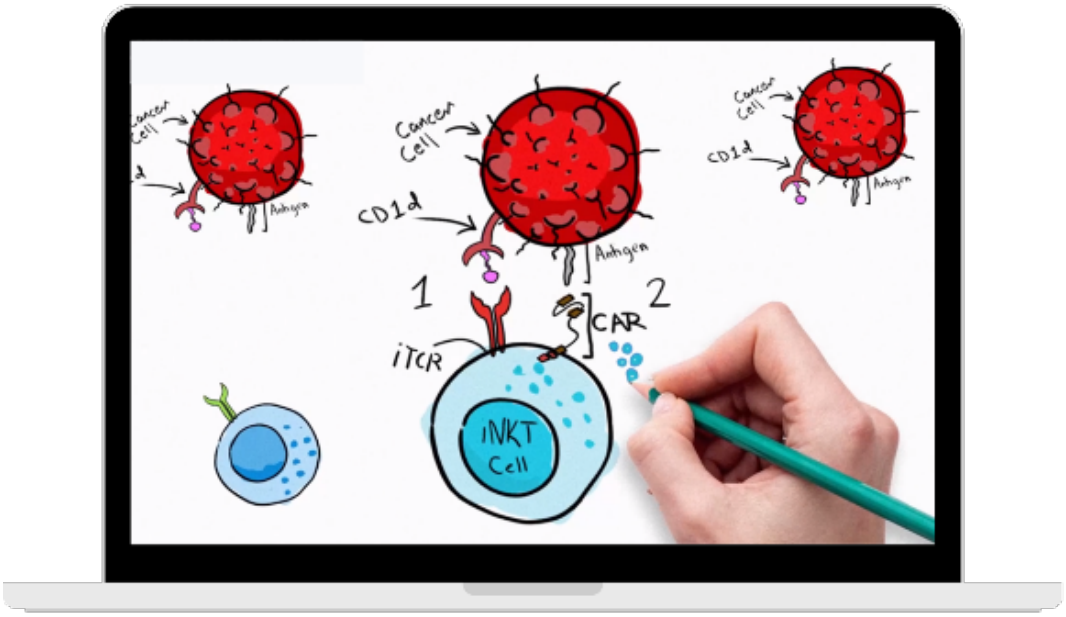
continued its manufacturing process development and scale-up activities and this process optimisation remains on track to support the clinical manufacture of ALA-101 for phase I clinical trials in H1 CY24.

INVESTOR RELATIONS AND NEWS

Over the quarter, CEO Dr Michael Baker presented at several investor events, including AusBiotech Invest, Capital Network's Emerging ASX Gems conference and the Monsoon Twilight Investor Briefing. Copies of these presentations are available on the Company's website.

The Company also prepared an explanatory video to help investors learn more about the cell therapy revolution and how iNKT cells, in conjunction with Chimeric Antigen Receptors (CARs), are well positioned to address substantial unmet need for cancer treatment. You can watch the video on the Company's website and by clicking on the image below.



In December, Arovella also held a webinar with the inventor of its iNKT technology, Prof. Anastasios Karadimitris, describing details of new research he presented at the American Society of Hematology (ASH) Annual Meeting. A recording of the webinar is available on the Company's website and by clicking on the image below.

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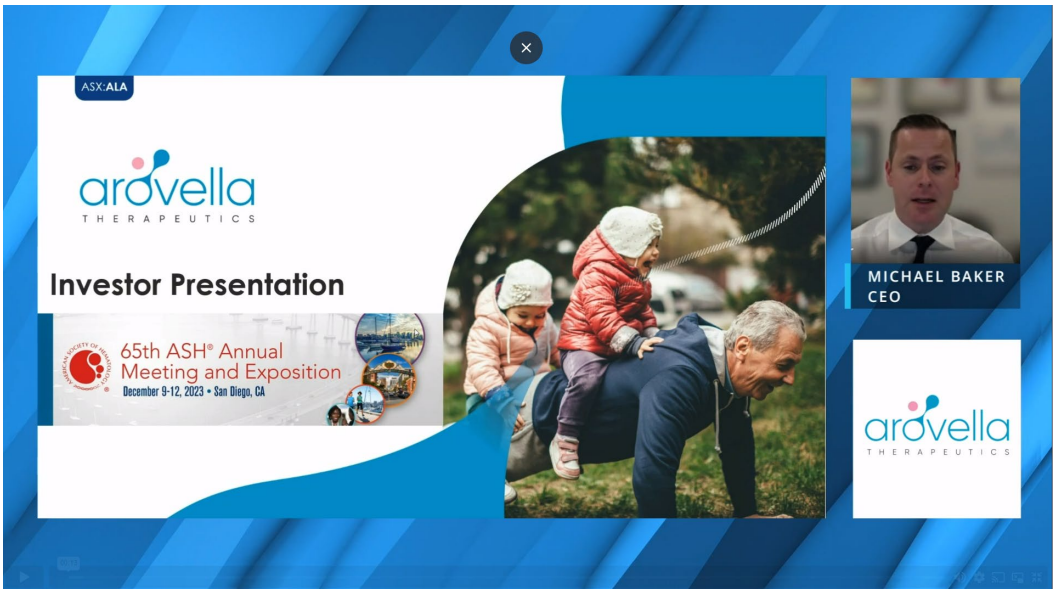

NEW CFO AND COMPANY SECRETARY

On 1 December 2023, Arovella appointed Tim Luscombe as Chief Financial Officer (CFO) and Company Secretary. Tim is a Director at Bio101 Financial Advisory (Bio101), a financial services firm providing outsourced CFO, taxation and company secretarial solutions to the Healthcare sector. Tim has more than 10 years of finance and commercial experience working with public and private companies in Australia and abroad. He currently serves as a CFO and Company Secretary for several ASX listed, public unlisted and private Healthcare companies. Tim holds a Bachelor of Commerce from the University of Melbourne and a Certificate in Governance Practice from the Governance Institute of Australia and is a qualified Chartered Accountant.

FINANCIAL UPDATE

Arovella continues to be in a solid financial position with a closing cash balance at the end of the December quarter of $4.76 million, compared to $5.32 million at the end of the previous quarter. The net cash used in operating activities during the quarter was $0.65 million compared with $1.99 million for the previous quarter to 30 September 2023 due to receipt of the Company's R&D Tax Incentive rebate for FY23. Expenditure on R&D and staff costs totalling $2.25 million represented 83% of the Company's total expenditure.

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, remuneration and superannuation at commercial rates.

For and on behalf of the Board and for further information, please contact:

Dr Michael Baker
Chief Executive Officer & Managing Director
Arovella Therapeutics Ltd
investor@arovella.com

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 is also expanding into solid tumour treatment through its CLDN18.2-targeting technology licensed from Sparx Group. Additional tumour targeting technologies are anticipated to be used in conjunction with Arovella's iNKT cell therapy platform. 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. 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; **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.

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	**Quarter ended ("current quarter")**
35 090 987 250	31 December 2023

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(1,959)	(3,316)
	(b) product manufacturing and operating costs	-	(4)
	(c) advertising and marketing	(28)	(75)
	(d) leased assets	-	-
	(e) staff costs	(289)	(709)
	(f) administration and corporate costs	(421)	(696)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	47	74
1.5	Interest and other costs of finance paid		
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	1,935	1935
1.8	Other (GST)	69	160
1.9	**Net cash from / (used in) operating activities**	**(647)**	**(2,632)**

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 (6 months) $A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(35)	(35)
	(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)	(50)	(50)
2.6	**Net cash from / (used in) investing activities**	**(85)**	**(85)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	2,216
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	186	186
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(8)	(121)
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 (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**178**	**2,281**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	5,315	5,175
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(647)	(2,632)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(85)	(85)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	178	2,281
4.5	Effect of movement in exchange rates on cash held	2	24
4.6	**Cash and cash equivalents at end of period**	**4,763**	**4,763**

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	483	5,315
5.2	Call deposits	4,280	-
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)**	**4,763**	**5,315**

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	121
6.2	Aggregate amount of payments to related parties and their associates 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.

The amount at 6.1 includes Director fees and salary (including superannuation) for the CEO and Managing Director and Non-Executive Directors.

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**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)	(647)
8.2	Cash and cash equivalents at quarter end (item 4.6)	4,763
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	4,763
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	7.4

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:

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

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.

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: 25 January 2024

Authorised by: Board of Directors
(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.