ASX Release

25 July 2024

APPENDIX 4C: FOURTH QUARTER FY 2024

Highlights for the quarter:

- **Strong cash position of $12.7 million in cash and cash equivalents at the end of the quarter**
- **Achieved critical milestone by completing process development to define a clinic-ready manufacturing process for ALA-101 and the CAR-iNKT cell platform**
- **Presented new data at the American Association for Cancer Research (AACR) Annual Meeting describing the potential benefits of ALA-101**
- **Appointed Professor Gianpietro Dotti, a pioneer of CAR-iNKT cell development and inventor of the IL-12-TM technology, to the Scientific Advisory Board**

MELBOURNE, AUSTRALIA 25 July 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 fourth 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 funding of $12.7 million as of 30 June 2024. This is expected to provide Arovella with sufficient funding to obtain preliminary data in its planned first-in-human clinical trial for ALA-101.

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

- Manufacture clinical batches of ALA-101 for phase 1 clinical trials;
- Securing a regulatory acceptance with the FDA/TGA to conduct a phase 1 clinical trial in CD19-positive blood cancers;
- Commence a phase 1 clinical trial for ALA-101 in patients with CD19-positive blood cancers;
- Present preclinical proof-of-concept data for its gastric cancer CLDN18.2-iNKT program, and;
- Present preclinical proof-of-concept data for IL-12-TM as an armouring technology for Arovella's CAR-iNKT cell platform.

DEVELOPING A CLINIC-READY CAR-iNKT MANUFACTURING PLATFORM

During the quarter, Arovella achieved a critical milestone by completing process development for its patent-protected manufacturing process required for large-scale Good Manufacturing Practice (GMP) manufacturing of its lead product, ALA-101. This is a significant step in taking ALA-101 into clinical trials and establishing the CAR-iNKT cell platform for use across various tumour targets.

Corporate One, 84 Hotham Street, Preston, VIC 3072 Australia
Telephone: + 61 3 9863 6472
investor@arovella.com | www.arovella.com

The modular, semi-automated process, developed at Cell Therapies Pty Ltd, is suitable for large-scale manufacturing and produces a high yield of Chimeric Antigen Receptor (CAR)-positive iNKT cells with very high purity. A well-controlled and reproducible GMP manufacturing process is essential for regulatory approval for first-in-human clinical trials. Arovella can now proceed with engineering and GMP batches to produce material for phase 1 clinical trials. The manufacturing process uses well-known automated cell therapy equipment, significantly reducing technology transfer risks to new jurisdictions.

Manufacturing process outcomes:

- **High yield,** >5,000-fold expansion of CAR-iNKT cells
- **>60%** of the cells **have the CAR** (i.e. CAR-iNKT cells)
- **>99% purity** of iNKT cells
- **Semi-automated,** suitable for **large-scale production**
- **Lentiviral vector agnostic,** meaning that a similar process can be used to generate additional products to target different cancer types
- Potential to leverage **FDA Platform Designation**

The final product characteristics are consistent with the expectations of global regulators such as the US FDA for product quality and safety. The process maintains the beneficial highly cytotoxic CD4-negative population of iNKT cells, as described in Arovella's licensed patents, that have been shown to be more cytotoxic than CD4-positive cells in a recent presentation at the American Association for Cancer Research (AACR) Annual Meeting. The expectation is that a balanced product with a mix of these cell phenotypes may lead to superior efficacy.

Achievement of this milestone will facilitate Arovella's pipeline expansion for its CAR-iNKT cell platform. The manufacturing process can be applied to Arovella's future CAR-iNKT cell products, significantly reducing the time required to proceed from proof-of-concept data to clinical manufacture for programs with new CARs. As the manufacturing process is lentiviral vector agnostic, it enables the use of newly developed CARs, or CARs from other programs capable of recognising different tumour types that can be added to iNKT cells (for example, Claudin 18.2-targeting CAR-iNKT cells).

TAKING ALA-101 INTO THE CLINIC

Arovella has commenced preparatory activities for its phase 1 first-in-human clinical trial to treat patients with CD19-positive blood cancers. During FY25, Arovella will focus on bringing ALA-101 into the clinic. The key activities to be conducted over the coming months are outlined in the figure below.

Corporate One, 84 Hotham Street, Preston, VIC 3072 Australia
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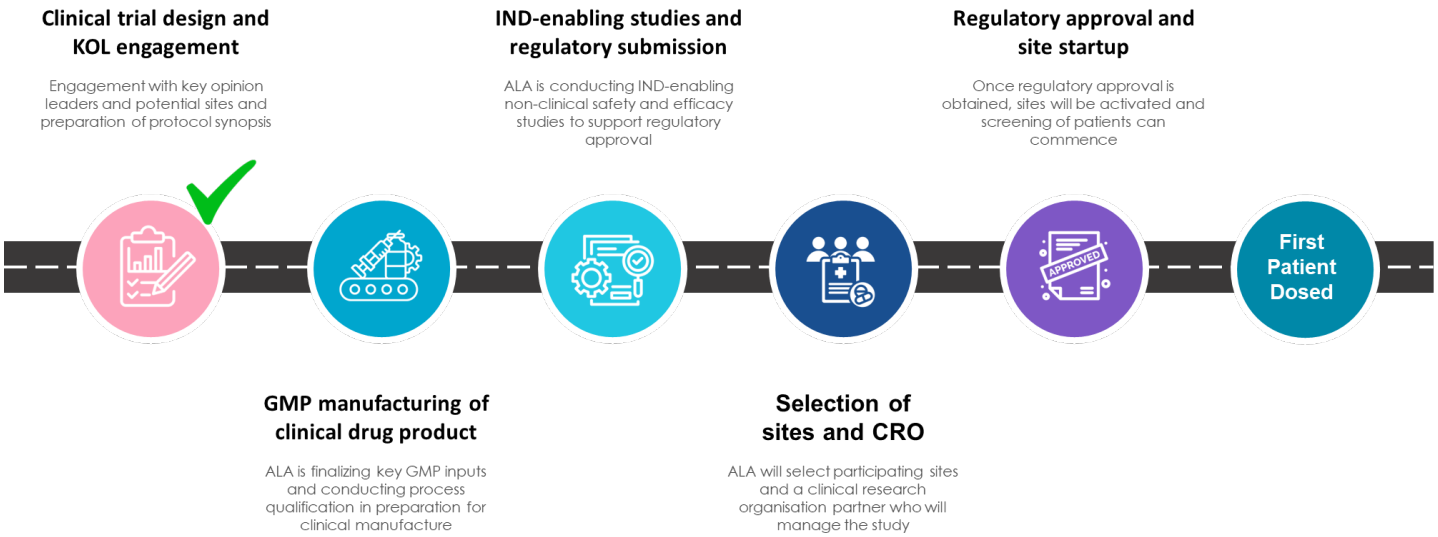

NEW DATA PRESENTED AT AACR

In April, Arovella presented new pre-clinical data characterising ALA-101 at the AACR Annual Meeting in San Diego. The data summarised two distinct phenotypes of cells within the drug product, each playing a different role in responding to tumour cells. In particular, ALA-101 CAR-iNKT cells were separated based on whether or not they produced CD4 on their surface (CD4+ vs CD4-). Cells negative for CD4 (CD4-) were better able to kill target tumour cells via the CD19 Chimeric Antigen Receptor (CAR). In contrast, CD4+ cells proliferated faster in response to CD19+ tumour cells. The two groups of cells also produced a different cytokine response following CAR activation.

The outcomes of these studies have shown encouraging results, supporting the potential benefit of having diverse subsets among CAR19-iNKT cells for treating CD19+ cancers. Arovella's proprietary iNKT manufacturing method is designed to maintain the highly cytotoxic CD4- population, thus maintaining a healthy balance of cells with different mechanisms of responding to tumour cells.

A copy of the poster is available on the Company's website https://www.arovella.com/news-presentations.

STRENGTHENING THE AROVELLA TEAM AND SCIENTIFIC ADVISORY BOARD

Dr Michelle Ferguson

Dr Ferguson holds a PhD in Immunology from the University of Adelaide, Australia, and has 15+ years of experience in academia, private translational research institutes, and the industry. Before joining Arovella, Dr Ferguson worked with Tessa Therapeutics, a clinical-stage biotechnology company in Singapore, developing next-generation cell therapies to treat haematological cancers and solid tumours. Her prior roles have encompassed discovery research, preclinical development, and process development for autologous CAR-T and allogeneic CAR-EBVST cell therapy platforms. She joins Arovella as Director of Research and Development.

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Dr Kelvin Yip

Dr Yip joins the team as the Associate Director of Research and Development. After graduating with a PhD at the University of Melbourne, he spent seven years in cancer discovery research at Monash Biomedicine Discovery Institute. Throughout his journey, he has spearheaded projects to understand the intricate mechanisms of tumour biology and develop combination therapies to reverse therapy resistance. Leveraging his core expertise and industry experience, his role is to advance research projects and identify opportunities for Arovella's pipeline expansion.

Professor Gianpietro Dotti

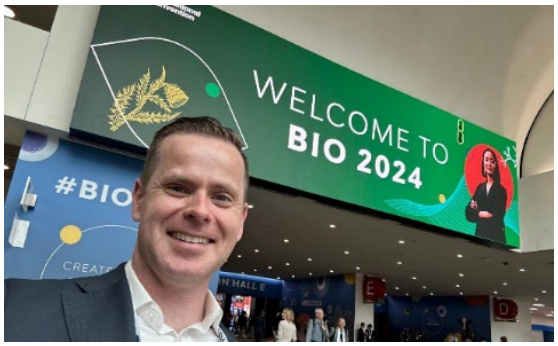
In April, Arovella announced that it had appointed Professor Gianpietro Dotti to its Scientific Advisory Board. Professor Dotti's appointment strengthens Arovella's expertise in using CAR-iNKT cells to treat blood cancers and solid tumours. Professor Dotti is a pioneer and one of the first individuals to create CAR-iNKT cell strategies for cancer treatment. He has been involved in developing two products using CAR-iNKT cells used in blood cancer patients and paediatric patients with neuroblastoma.

Professor Dotti has spent over twenty years using his medical and scientific training to create engineered immune cells for cancer treatment. His research has led to more than 200 peer-reviewed articles, and he has consistently received the Highly Cited Researchers (Top 1%) award from Web of Science, Clarivate Analytics in 2020, 2021, 2022, and 2023.

Professor Dotti received his medical degree from the University of Milan, Italy and completed his clinical training and Board certification in haematology from the University of Parma. He completed his post-doctoral fellowship at the Center for Cell and Gene Therapy at the Baylor College of Medicine in Houston, Texas. Professor Dotti is a Professor of Microbiology and Immunology and the Director of the Cellular Immunotherapy Program at Lineberger Comprehensive Cancer Center at the University of North Carolina.

INVESTOR RELATIONS AND NEWS

In June, CEO and MD Dr Michael Baker joined the Australian delegation for BIO 2024 in San Diego, USA. BIO is the premier global biotechnology partnering event, and Dr Baker used the opportunity to meet with potential investors, strategic partners and collaborators.



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During the quarter, Dr Baker also presented to investors in Singapore and Hong Kong. In July, Dr Baker presented a non-deal roadshow in Perth, Brisbane, Sydney, and Melbourne to update investors on Arovella's achievements in manufacturing process development and its pathway to clinic. A copy of the presentation can be found on the Company's website or viewed by clicking on the image below.

In January, Arovella moved into its new office at Jumar Incubator. Jumar brings together a vibrant community of entrepreneurs within CSL's new flagship building, which houses its Global Headquarters and Centre for R&D. Arovella was fortunate to be selected to present at the official Jumar opening in April this year. Jumar was made possible thanks to investment from CSL, the Walter and Eliza Institute of Medical Research (WEHI), the University of Melbourne, and Breakthrough Victoria.

During the quarter, Spark Plus prepared a desk note describing Arovella's current product pipeline and its ambitions to tackle a range of blood cancers and solid tumours.

View Spark Plus desk note.

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TERMINATION OF THE TEVA LICENSE AGREEMENT

On 13 June 2024, the Company announced a settlement agreement with Teva Pharmaceuticals, which included the immediate termination of the Licence Agreement, a US$300,000 by Arovella to Teva reflecting the initial upfront and option fee initially paid by Teva and the assignment of a Market Authorisation from Teva to Arovella for the ZolpiMist product in Chile. The Company was pleased to conclude both parties' obligations under the agreement, given that ZolpiMist is a legacy product that SUDA Ltd was trying to commercialise in 2017.

FINANCIAL UPDATE

- Arovella continues to be in a solid financial position, with a closing cash balance of $12.7 million at the end of the June quarter.

- The net cash outflow in operating activities during the quarter was $1.82 million, compared with $2.45 million for the previous quarter to 31 March 2024.

- R&D and staff costs totalling $1.51 million represented 82% of the Company's total operating outflows, excluding the costs associated with capital raising.

On 26 March 2024, Arovella announced that it had completed a Placement to institutional and sophisticated investors to raise approximately $12.5 million (before costs) under a placement of 125 million new fully paid ordinary shares in the Company (Shares) at A$0.10 per Share (Placement), with an attaching 1-for-1 Option with an exercise price of $0.15 (a 50% premium to the Placement price) and an exercise period of three years.

The Placement received strong support from domestic and international institutional and sophisticated investors. Funds raised under the Placement will be used to progress Arovella's lead product, ALA-101, into a Phase 1 clinical trial and generate preliminary data from patients dosed with ALA-101. Funds raised under the placement will also be used to strengthen Arovella's iNKT cell therapy pipeline and advance Arovella's solid tumour products and for general working capital purposes.

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

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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. 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 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

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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investor@arovella.com | www.arovella.com

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	30 June 2024

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(1,162)	(6,331)
	(b) product manufacturing and operating costs	-	(4)
	(c) advertising and marketing	(40)	(156)
	(d) leased assets	-	-
	(e) staff costs	(345)	(1,363)
	(f) administration and corporate costs	(292)	(1,388)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	24	138
1.5	Interest and other costs of finance paid		
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives		1,935
1.8	Other (GST)	(9)	260
1.9	**Net cash from / (used in) operating activities**	**(1,824)**	**(6,909)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(4)	(128)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 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 (provide details if material)		(50)
2.6	**Net cash from / (used in) investing activities**	**(4)**	**(178)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	12,500	14,716
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	23	803
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(786)	(918)
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 (reallocation 3.1 for Placement funds received in March quarter when shares were issued in April 2024)	(615)	-
3.10	**Net cash from / (used in) financing activities**	**11,122**	**14,601**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	3,420	5,175
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,824)	(6,909)

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(4)	(178)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	11,122	14,601
4.5	Effect of movement in exchange rates on cash held		25
4.6	**Cash and cash equivalents at end of period**	**12,714**	**12,714**

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	98	1,351
5.2	Call deposits	12,616	2,069
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)**	**12,714**	**3,420**

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	159
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)	(1,824)
8.2	Cash and cash equivalents at quarter end (item 4.6)	12,714
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	12,714
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	7.0

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.

25 July 2024

Date: .....

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.