

## AROA BIOSURGERY DECEMBER 2023 4C – COMMENTARY

### Financial Highlights

- Strong ~**20% increase in quarter-on-quarter cash receipts from customers**, to NZ\$17.7 million.
- **Continued quarter-on-quarter progress towards breakeven operational cashflows**, with net cash outflows from operations decreasing to NZ\$1.7 million from \$3.2 million in the prior quarter.
- Net cash outflows from investing activities of NZ\$1.1 million for the quarter, reflecting further investment into additional manufacturing plant & equipment capacity.
- Strong cash balance of **NZ\$30.5 million** as at 31 December 2023, and the Company is debt-free.

### Updated FY24 Full-Year Guidance

- Guidance reduced to NZ\$67-70 million total revenue, NZ\$66-69 million product revenue, 85% product gross margin and a normalised EBITDA<sup>1</sup> loss of NZ\$1-3 million.<sup>2</sup>
- One-off (H2 FY24) decrease in expected revenue from TELA Bio, Inc. ('TELA Bio') due to a previous overestimation of AROA's revenue share (non-cash) on inventory supplied to TELA Bio and a delay to a joint product development project. OviTex<sup>TM3</sup> and OviTex PRS remain on a strong growth trajectory.<sup>4</sup>
- Robust Myriad<sup>TM</sup> sales performance, with 10% growth in Myriad active accounts from Q2 to Q3, comparable field sales productivity and a revised forecast of **70-85%** year-on-year growth (full-year).

### Operational Highlights

- US FDA ('FDA') 510(k) clearance received for a new product, a resorbable dental barrier developed and manufactured from the Company's proprietary AROA ECM<sup>TM</sup> platform technology. The Company is actively pursuing a new partnership to commercialise this product.
- The FDA has reviewed AROA's 510(k) application for Myriad Flow<sup>TM</sup>, a new soft tissue regeneration product that could be commercialised in combination with Enivo<sup>TM</sup>, and requested additional pre-clinical and clinical data to support a clearance. Both studies appear to be less complex than anticipated with regulatory clearances expected within 24 months.
- To date, six patients (n=10) enrolled in the pilot clinical study for Enivo, AROA's new tissue apposition platform technology, have undergone a unilateral mastectomy and completed follow-up care, with no clinically relevant seroma or complications reported.
- 36 patients enrolled in AROA's Myriad Augmented Soft Tissue Regeneration Registry ('MASTRR') during the quarter, taking the total number of participants to 268 (n=300).

<sup>1</sup> Normalised EBITDA is non-conforming financial information, as defined by the NZ Financial Markets Authority, and has been provided to assist users of financial information to better understand and assess the AROA Group's ("Group") comparative financial performance without any distortion from NZ GAAP accounting treatment specific to one-off fair value adjustments, one-off transaction costs associated with capital raisings. The impact of non-cash share-based payments expense and unrealised foreign currency gains or losses have also been removed from the profit or loss. This approach is used by Management and the Board to assess the Group's comparative financial performance. All references in this announcement to 'normalised EBITDA' are as set out in this footnote.

<sup>2</sup> This guidance is presented on a reported basis, reflects an expected NZ\$/US\$ exchange rate of 0.62 for H2 FY24 and is subject to TELA Bio delivering on its CY23 revenue guidance of US\$57-60 million (reflecting 38-45% growth over CY22).

<sup>3</sup> OviTex and TELA Bio are trademarks of TELA Bio, Inc.

<sup>4</sup> TELA Bio's Q3 CY23 revenue represented its 11th consecutive quarter of at least 35% year-on-year growth (TELA Bio press release dated 9 November 2023).



- Enrolments in AROA's multi-center Symphony™ randomised control trial approximately doubled during the quarter, with a total of 86 participants enrolled to date (n=120).
- 11 key industry conferences, including the American Society of Plastic Surgeon's Annual Meeting and the American College of Surgeons' 2023 Clinical Congress.
- Experienced US clinical executive, Dr Adam Young, appointed as inaugural VP, Medical Affairs. Dr Young brings deep academic and commercial expertise, with a focus on the use of extracellular matrices for wound healing and soft tissue reconstruction.
- Successful DEKRA audit of AROA's San Diego (US) site.
- An active investor relations schedule during the quarter, including an informational presentation by Brian Ward (CEO) at the Jeffries Healthcare Conference in London (UK) and two well-attended AROA-hosted events.
- Winner of 'Excellence in Innovation' and 'Supreme Business Excellence' at the 2degrees Auckland Business Awards (South and East Region).
- AROA will host a webinar to discuss these results today at 9 a.m. AEST. [Click here to register.](#)

Soft tissue regeneration company Aroa Biosurgery Limited (ASX: ARX, 'AROA' or the 'Company') is pleased to provide an update on its activities for the quarter ended 30 December 2023.

#### Cashflow commentary

Q3 FY24 cash receipts from customers of NZ \$17.7 million, reflecting a strong ~20% increase on the prior quarter (NZ\$14.8 million). The increase in cash receipts was driven by the increase in Myriad and OviTex/OviTex PRS sales.

Net cash outflows from operations reduced to NZ\$1.7 million for the quarter, compared to NZ\$3.2 million in the previous quarter and in line with the Company's expected decrease in net operating cash outflows towards breakeven by the end of FY24. Net operating cash outflows for the quarter included increases in 'cash paid for staff costs', reflecting tactical headcount expansion in the field sales team and increases in commission payments for sales growth. 'Cash paid for advertising and marketing' also increased, reflecting an increase in clinical study expenses and marketing expenses for the quarter.

Net cash outflows from investing activities for Q3 FY24 were NZ\$1.1 million, primarily reflecting AROA's investment into additional manufacturing plant & equipment capacity.

AROA ended the quarter with a strong cash balance of NZ\$30.5 million, and the Company is debt-free.

In accordance with ASX Listing Rule 4.7C.3, AROA advises that an aggregate amount of NZ\$178,000 was paid during the quarter to the Company's six non-executive directors for directors' fees.

#### Outlook

AROA is updating its FY24 full-year guidance for total revenue, product revenue, product gross margin and a normalised EBITDA loss to NZ\$67-70 million, NZ\$66-69 million, 85% and NZ\$1-3 million respectively.<sup>2</sup> Previous guidance (published on 28 November 2023) was in the range of NZ\$73-76 million, NZ\$72-75 million, 85% and NZ\$1-2 million [profit].

This reflects a one-off (H2 FY24) decrease in expected revenue from TELA Bio due to a previous overestimation of AROA's revenue share (non-cash) on inventory supplied to TELA Bio and a delay to a joint product development project. OviTex and OviTex PRS remain on a strong growth



trajectory<sup>5</sup> but the Q3 data has identified the need for a re-calibration to better align AROA's revenue share estimation with TELA Bio's recent inventory management measures.

AROA's US commercial operations is expected to deliver strong 70-85% year-on-year (full-year) Myriad sales growth.

CEO, Brian Ward commented "Whilst we now anticipate a more moderate FY24 performance, this is a short-term dynamic and we expect to return to the previous trajectory from the next quarter (Q1 FY25).

OviTex and OviTex PRS sales are on a strong growth pathway and we are confident this will continue. The transitional impact of TELA Bio's inventory management measures has hit us this year but having now been flushed out, growth will return in FY25 with demand re-aligning with TELA Bio's sales.

Myriad sales performance remains robust, with 10% growth in Myriad active accounts from Q2 to Q3, comparable field sales productivity and a strong revised full-year forecast. The product offering is compelling and demonstrating stickiness with the customers we have converted. As we continue to build our field sales expertise, we are focused on rapidly actioning insights gained to escalate sales productivity and drive increased growth."

#### 510(k) clearance for new dental product

AROA has received FDA 510(k) clearance for a resorbable dental barrier manufactured from the Company's proprietary AROA ECM™ platform technology. The product is intended for use in guided tissue regeneration and guided bone regeneration in dental and periodontal procedures.

Dental barriers are currently available in permanent or resorbable formats, with the latter removing the need for a second surgery. Within the resorbable category, extracellular matrix ('ECM') based products provide favorable characteristics including a preferred handling profile and the potential for lower pain.<sup>6</sup> A systematic review of 21 studies conducted on 375 patients on the use of ECM-based barriers found that they are effective in treating oral soft tissue defects, including guided tissue regeneration procedures.<sup>7</sup> The value of the global dental barrier membrane market is estimated to be at least US\$400 million.<sup>8</sup>

Brian Ward says "We are pleased to demonstrate that we can continue to leverage further value from our AROA ECM technology through new regulatory clearances and by developing new commercial partnerships. We are actively pursuing a new partnership to commercialise this product."

#### Enivo

Six patients (of a target of ten) enrolled in the Enivo pilot clinical study have undergone a unilateral mastectomy and completed their follow-up care, with no clinically relevant seroma or complications reported. A second New-Zealand based study site was also added during the quarter.

Seromas are a common post-surgical complication that can disrupt healing, increase pain, cause

<sup>5</sup> TELA Bio's Q3 CY23 revenue represented its 11th consecutive quarter of at least 35% year-on-year growth (TELA Bio press release dated 9 November 2023).

<sup>6</sup> Alauddin MS, et al. Barrier Membrane in Regenerative Therapy: A Narrative Review. *Membranes* (Basel). 2022;12(5).

<sup>7</sup> Gulameabasse, S, et al., Chorion and amnion/chorion membranes in oral and periodontal surgery: A systematic review. *J Biomed Mater Res B Appl Biomater*, 2021. 109(8): p. 1216-1229.

<sup>8</sup> iData Research. (2021). Dental Barrier Membrane Market Size, Share, and COVID-19 Impact Analysis | Global | 2021-2027 | MedCore | Includes: Resorbable, and Non-Resorbable Dental Barrier Membranes. <https://idataresearch.com/product/global-dental-barrier-membrane-market/>, Coherent Market Insights. (2022). Dental Membrane and Bone Graft Substitute Market Analysis. <https://www.coherentmarketinsights.com/market-insight/dental-membrane-and-bone-graft-substitute-market-1143>.



swelling and result in poor cosmetic outcomes. They can also lead to more severe complications such as infections, and require extended hospital stays. Surgeons currently use surgical drains, adhesives, or quilting sutures to manage the seroma risk, but these techniques can be unreliable so post-operative complications continue to pose significant challenges. These initial pilot study results, coupled with the results of AROA's peer-reviewed pre-clinical study,<sup>9</sup> indicate the unique clinical potential of the Enivo system to address an unmet need.

As previously communicated, AROA submitted a FDA 510(k) application for Myriad Flow™, a new Myriad product that could be commercialised in combination with the previously FDA-cleared components of the Enivo system. The FDA has reviewed that submission and requested additional pre-clinical and clinical data to support a clearance. AROA expects to continue engaging with the FDA to confirm the design of each study and then provide an update to the market on costs and timeframes.

CEO, Brian Ward commented "We are very encouraged by the FDA's feedback and what we understand to be their outstanding questions. Further details need to be discussed, but at this stage, we are pleased that both studies appear to be less complex than anticipated with regulatory clearances expected within 24 months. Myriad Flow and Enivo continue to be important products for our long-term strategy."

#### Myriad and Symphony activity

AROA's clinical trials progressed well during the quarter. 268 (of a target of 300) patients were enrolled into MASTRR by the end of the quarter and patient enrolments into the Symphony randomized control trial almost doubled to 86 (up from 42 at the end of the previous quarter, of a target of 120). MASTRR is AROA's largest prospective study to date, evaluating Myriad Matrix™ and Myriad Morcells™ (including short and long-term healing outcomes) in a wide range of surgical specialties and procedures. The Symphony trial is an 18-month multi-center study assessing the product's efficacy in treating diabetic foot ulcers.

AROA's sales and clinical teams attended and presented in person, alongside key opinion leaders, at 11 key industry conferences around the world. Consistent with the Company's focus on the trauma opportunity for Myriad (estimated total addressable market of US\$300 million<sup>10</sup>), these included the American Society of Plastic Surgeon's Annual Meeting and the American College of Surgeons' 2023 Clinical Congress.

#### VP, Medical Affairs

Experienced US-based clinical executive appointed to the inaugural position of VP, Medical Affairs. Dr Young received his PhD in Biomedical Engineering from the University of California San Diego and has authored multiple scientific publications on the use of extracellular matrices for wound healing and soft tissue repair. Prior to joining AROA, Dr. Young held leadership positions in Medical Affairs and Research & Development at leading global regenerative medicine companies Integra LifeSciences and ACell, Inc.

#### DEKRA audit San Diego site

Global certification organization, DEKRA, audited and certified AROA's San Diego (US) premises following a site move in early 2023.

<sup>9</sup> Mason, I. T., et al. (2022). Evaluation of Tissue Apposition and Seroma Prevention in an Ovine Model of Surgical Dead Space Using a Novel Air-Purged Vacuum Closure System. *Eplasty*, 22.

<https://www.hmpgloballearningnetwork.com/site/eplasty/original-research/evaluation-tissue-apposition-and-seroma-prevention-ovine-model>.

<sup>10</sup> Management estimates.

### Investor relations

AROA maintained an active investor relations schedule during the quarter, including an informational presentation by CEO, Brian Ward, at the London Jeffries Healthcare Conference. The Company hosted two well-attended events, with a Sydney (AU) presentation featuring a prominent US-based trauma surgeon and a site visit by members of the New Zealand Shareholders Association.

### Business awards

AROA won the 'Excellence in Innovation' and 'Supreme Business Excellence' categories at the 2degrees Auckland Business Awards (South and East Region).

### Quarterly webinar

The Company will hold a webinar with CEO Brian Ward and CFO James Agnew today, Tuesday 30 January at 9 a.m. AEST to discuss the December Quarterly Results.

**Investors can register for the webinar via the following link:**

[https://us02web.zoom.us/webinar/register/WN\\_6C1SiK4HQy6fPgEFv9KamA](https://us02web.zoom.us/webinar/register/WN_6C1SiK4HQy6fPgEFv9KamA)

Questions can be submitted prior to the webinar to [investor@aroa.com](mailto:investor@aroa.com) or live, via the Q&A function on Zoom.

**<ENDS> Authorised on behalf of the Aroa Biosurgery Board of Directors by Brian Ward, CEO.**

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### About AROA™

Aroa Biosurgery is a soft-tissue regeneration company committed to 'unlocking regenerative healing for everybody'. We develop, manufacture, sell and distribute medical and surgical products to improve healing in complex wounds and soft tissue reconstruction. Our products are developed from a proprietary AROA ECM™ technology platform, a novel extracellular matrix biomaterial derived from ovine (sheep) forestomach.

Over 6 million AROA products have been used globally in a range of procedures to date, with distribution into our key market of the United States via our direct sales force and our partner TELA Bio, Inc. Founded in 2008, AROA is headquartered in Auckland, New Zealand and is listed on the Australian Securities Exchange (ASX: ARX). [www.aroa.com](http://www.aroa.com)

### About Myriad™

Myriad Matrix™ is an extracellular matrix graft, composed of AROA ECM and designed for soft tissue reconstruction and complex wounds. Myriad Morcells™ is a morcellised version of Myriad Matrix that easily conforms to optimize contact with irregular wound beds. Myriad Morcells Fine is a morselized conformable ECM graft that can be used either by itself or synergistically with Myriad Matrix.



**About Endoform™**

Endoform™ products are unique extracellular matrix products, composed of AROA ECM, for the management of acute and chronic wounds.

**About Symphony™**

Symphony is a new product which has been developed off the strength of AROA ECM. It is applied as a graft and is surgically fixed at the margins. It is designed to support healing during the proliferative phase to reduce time to wound closure, particularly in patients whose healing is severely impaired or compromised due to disease.

**About Enivo™**

This is a new Tissue Apposition Platform which AROA is developing, designed to close tissue cavities at a surgical site created by surgical dissection or tissue removal. It is comprised of a specially designed AROA ECM implant that is coupled to an external single-use negative pressure pump.

When the product is deployed, the tissue surfaces are drawn together, held in place and tissue fluids are carried by the vacuum to an external fluid collection bag. AROA intends to develop and launch a new class of products utilising this new platform technology.

**About OviTex™ and OviTex PRS**

OviTex and OviTex PRS are reinforced bioscaffolds manufactured by AROA. The products are based on AROA ECM technology, co-developed with our partner, TELA Bio, Inc. (US) and sold by TELA Bio in the United States and Europe. TELA Bio is licensed to sell OviTex for abdominal wall reconstruction and hernia repair. Since the first hernia product was launched in 2016, the portfolio has expanded to include hernia products for minimally invasive surgery (robotic) and the launch of OviTex PRS (licensed to TELA Bio for breast reconstruction).

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## Appendix 4C

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

#### Name of entity

Aroa Biosurgery Limited

#### ABN

ARBN 638 867 473

#### Quarter ended ("current quarter")

31 December 2023

Consolidated statement of cash flows	Current quarter \$NZ'000	Year to date (9 months) \$NZ'000
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	17,729	47,725
1.2 Payments for		
(a) research and development	(433)	(1,337)
(b) product manufacturing and operating costs	(1,227)	(6,261)
(c) advertising and marketing	(4,059)	(10,502)
(d) leased assets	(7)	(16)
(e) staff costs	(12,153)	(34,237)
(f) administration and corporate costs	(1,879)	(6,203)
1.3 Dividends received (see note 3)	-	1
1.4 Interest received	494	1,513
1.5 Interest and other costs of finance paid	-	(10)
1.6 Income taxes paid	(212)	(486)
1.7 Government grants and tax incentives	-	84
1.8 Other (rent received)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,747)</b>	<b>(9,729)</b>

#### 2. Cash flows from investing activities

##### 2.1 Payments to acquire or for:

(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(1,059)	(3,170)
(d) investments	-	-
(e) intellectual property	(47)	(493)

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Consolidated statement of cash flows		Current quarter \$NZ'000	Year to date (9 months) \$NZ'000
	(f) other non-current assets	-	-
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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>(1,106)</b>	<b>(3,663)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	3	21
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	41
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 (lease liability payments)	(302)	(916)
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>(299)</b>	<b>(854)</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	33,955	44,722
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,747)	(9,729)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(1,106)	(3,663)



Consolidated statement of cash flows		Current quarter \$NZ'000	Year to date (9 months) \$NZ'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(299)	(854)
4.5	Effect of movement in exchange rates on cash held	(317)	10
4.6	<b>Cash and cash equivalents at end of period</b>	<b>30,486</b>	<b>30,486</b>

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 \$NZ'000	Previous quarter \$NZ'000
5.1	Bank balances	10,486	3,955
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (term deposits less than 90 days)	20,000	30,000
5.5	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>30,486</b>	<b>33,955</b>

6.	Payments to related parties of the entity and their associates	Current quarter \$NZ'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	178
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>		

<b>7. Financing facilities</b>	<b>Total facility amount at quarter end \$NZ'000</b>	<b>Amount drawn at quarter end \$NZ'000</b>
<i>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.</i>		
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	931	389
7.3 Other (please specify)	-	-
<b>7.4 Total financing facilities</b>	<b>931</b>	<b>389</b>
<b>7.5 Unused financing facilities available at quarter end</b>		<b>542</b>
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.		
Includes the following: N/A		

<b>8. Estimated cash available for future operating activities</b>	<b>\$NZ'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	(1,747)
8.2 Cash and cash equivalents at quarter end (item 4.6)	<b>30,486</b>
8.3 Unused finance facilities available at quarter end (item 7.5)	542
8.4 Total available funding (item 8.2 + item 8.3)	31,028
<b>8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>18</b>
<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 January 2024

Authorised by: By the board  
(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.