



#### **QUARTERLY ACTIVITIES & CASHFLOW REPORT**

#### **Highlights**

- Net positive cashflow recorded for the quarter boosted by increased cash receipts from operations over the previous quarter and receipt in July of the FY22 R&D tax rebate. Cash at bank increased by \$330K to \$7.1m at quarter-end, with no debt across the group.
- 34 new 3.0 tesla (3T) MRI scanners registered for services during the quarter, following the successful upgrade of the gold standard FerriScan® device to new generation 3T MRI machines. FerriScan®-3T was made available to clinicians globally from 25 July 2022 (see ASX release dated 25 July 2022).
- R&D costs of \$258K were higher than the \$147K recorded the previous quarter, driven by a focus on accelerating the fibrosis R&D project and product innovation projects, including the continued upgrade of the Company's regulatory cleared medical devices (SaMDs) to new generation 3T MRI machines.
- Work progressed on an accelerated growth strategy, culminating in the announcement and launch of 'Resonance Clinical' post-period, an initiative focussed on commercial objectives via the enhancement and expansion of service provision to clinical trials (see ASX release dated 25 October 2022).
- Discussions progressed with existing and potential new pharma customers to assist with their clinical trials and accelerated post-period with the launch of Resonance Clinical, by The Hon Minister Stephen Dawson, at the international/national AusBiotech conference in Perth, 26-28 October 2022.
- TGA requalification audit successfully completed, with the Company's suite of medical devices receiving renewed certifications through to 2024 or later, if so advised by the TGA.
- New websites for both Resonance Health (<u>www.resonancehealth.com</u>) and, post-period, for Resonance Clinical (<u>www.resonanceclinical.com</u>)

Resonance Health Ltd (ASX: RHT) ("Resonance Health" or the "Company") is pleased to release its Appendix 4C and Quarterly Activities & Cashflow Report for the quarter ended 30 September 2022.

#### **Continued strong demand for imaging services**

Resonance Health's imaging services continued in high demand during the quarter contributing to an increase in cash receipts from operations of \$160K over the June quarter and to positive cashflow for the quarter of \$184K versus an outflow of \$384K in the previous quarter. Sales receipts from operations were \$1.072M which was higher than both the June 2022 quarter and the prior corresponding quarter in 2021.

R&D costs were higher during the quarter at \$258K versus \$147K in the previous quarter, driven by a focus on accelerating the fibrosis R&D project and product innovation projects, including the continued upgrading of the Company's regulatory cleared software-medical-devices (SaMDs) to the new generation 3T MRI scanning machines. The Company's flagship medical device, FerriScan®, was launched on 3.0T MRI scanners and made available to clinicians and patients globally on 25 July 2022 (see below).



#### FerriScan® made available on 3 tesla (3T) MRI machines

On 25 July 2022, FerriScan®, the Company's best-selling device was made available to clinicians globally on 3.0T MRI scanning machines (see ASX release dated 25 July 2022). Since advising clinicians of this, the Company has onboarded 34 new MRI



scanners from existing and new customers, which speaks to the benefit of this production innovation.

The FerriScan® product innovation initiative commenced several years ago with studies to adapt the FerriScan® acquisition protocol from 1.5T to 3T MRI scanners, allowing for better usability of the FerriScan® service across the latest MRI machines. Despite being technically challenging, Resonance Health successfully finalised the calibration of the FerriScan® protocol, and FerriScan® is now commercially available for use in clinical trials and in the routine clinical management of patients, on both 1.5T and 3.0T MRI machines.

#### The gold standard in liver-iron-concentration analysis

FerriScan® is internationally recognised by clinicians and patients as the gold-standard for the analysis of liver-iron-concentration ("LIC") for patients suffering iron overload disorders. This accurate, MRI-based technique is non-invasive and eliminates the need for liver biopsies. FerriScan® is recommended in multiple clinical patient management guidelines and international standards of care.

Since the Company's inception, Resonance Health has completed approximately 60,000 FerriScan® analyses to assist patients suffering iron overload disorders around the world, and with pharmaceutical clinical trials. Until now, FerriScan® has only been available at MRI facilities with 1.5T field strength MRI scanning machines.

#### Prevalence of 3T MRI machines and market opportunity

3T MRI machines offer advantages for clinicians and patients, including shorter scan times and greater image contrast compared with 1.5T MRI machines and are growing in prevalence around the world. In the USA, 1.5T and 3T scanners are being purchased in approximately equal numbers, with 3T scanners already representing approximately 15% to 18% of total MRI scanners in Europe and North America.<sup>1</sup>

Resonance Health is committed to ensuring its services, including FerriScan®, are at the forefront of technical development, including being calibrated across new generation MRI machines, enabling service availability to as many patients as possible, so that their diseases can be managed effectively by their treating physicians. Ensuring that FerriScan® is available on as many MRI machines as possible is a key element of the Company's strategy to grow its clinical trial services contracts and revenue.

#### Development of FerriSmart® and Cardiac-T2\* for 3T

Work also progressed on the adaptation of FerriSmart®, the artificial intelligence ("AI") assisted evolution of FerriScan®, to 3T MRI scanning machines. This will improve availability + convenience for clinicians and patients in large new markets.



Work also commenced on the adaptation and calibration of CardiacT2\* to 3T machines, noting that many clinicians globally take advantage of the Company's bundled FerriScan® + CardiacT2\* service to obtain a more holistic view of the patient's iron overload status.

<sup>&</sup>lt;sup>1</sup> Could Very Low Field Strength Be the Next Frontier for MRI?, Burhan Ahmed Khan, M.D., Hyperfine intern, Eliot L. Siegel, M.D., Associate Vice Chair, University of Maryland School of Medicine, *Diagnostic Imaging*, 11 March 2021



#### Medical device development & innovation

Further progress was made towards completion of several product innovations in existing SaMD medical devices and services, aimed at broadening market access, driving new



market penetration, ensuring customer retention and enhancing patient and MRI centre outcomes.

Current priority projects include developing a new AI-assisted image analysis device, CardiacT2\*-AI, an AI version of the Company's reg-cleared Cardiac-T2\*, to complement the Company's three existing regulatory cleared AI devices; FerriSmart®, HepaFat-AI®, and LiverSmart®. The Company continues to target increased uptake of its highly scalable AI-assisted services through sales and marketing campaigns managed through the Resonance Health CRM software.

Once completed, the CardiacT2\*-Al product is expected to provide real-time analysis to assist clinicians in assessing cardiac-iron levels, which has been identified by the Thalassaemia International Federation ("TIF") as a critical and necessary requirement in large new markets where iron-overload diseases are prevalent. Through the Company's partnership with the Thalassaemia International Federation (see ASX release dated 12 November 2021), clinicians in new markets are requesting this capability.

Other product innovation initiatives include the improvement of HepaFat-Al® via a new liver segmentation module and the adoption of PDFF and steatosis outputs for HepaFat-Scan®. Work also continued validating a shorter MRI imaging protocol for FerriScan® and FerriSmart® with a potential 75% reduction in patient MRI scanner time, thereby improving patient experience and increasing scanner throughput. This has progressed successfully through the proof-of-concept stage, with the substantive development work now underway.

Work continued developing new FAST software, the Company's job management software, with upgrades also completed on the legacy FAST software, notably with the deployment of a new history report generation tool for FerriScan® to improve and streamline workflow of the Company's highly trained analysts.

#### Accelerated growth strategy

There was a continued, concerted focus on identifying and implementing initiatives to accelerate growth. This culminated in the launch post-period of Resonance Clinical, on 25 October 2022. The Resonance Clinical initiative is focussed on better commercial outcomes and higher returns through enhanced and expanded service provision to pharmaceutical companies engaged in clinical trials (see ASX release, 25 October 2022).

#### **Introducing 'Resonance Clinical'**

Resonance Clinical aims to capitalise on the lucrative and rapidly expanding global clinical trial marketplace, especially for new drugs and therapies being developed to treat liver diseases including iron-overload disorders and NAFLD/NASH, which is estimated to affect up to 30% of the global population<sup>2</sup>. This new initiative builds on Resonance Health's decades-long experience providing high-quality image-analysis and clinical trial services to pharma/biotech and their clinical trial management partners.

Resonance Clinical intends to provide full CRO services, as well as expanded imaging CRO and central laboratory CRO services to existing, as well as new pharmaceutical and biotech customers. This initiative, led by Program Director & Chief Scientist-Molecular Medicine, Dr Sherif Boulos, draws on expertise from across the Resonance Health group. These existing capabilities include PhD scientists (with biomedical and physics training), clinical researchers, trained medical laboratory scientists and a highly experienced QA/QC team.

As part of this initiative, equipment and personnel are being relocated from Murdoch University and UWA into a larger, purpose designed, dedicated Resonance Clinical laboratory at Bentley Tech Park in Perth. This

<sup>&</sup>lt;sup>2</sup> Nonalcoholic fatty liver disease and cardiovascular diseases phenotypes, Glandomenico Bisaccia et al, SAGE Open Medicine Volume 8: 1-15, 21 May 2020.



will deliver immediate cost-savings, provide greater autonomy, versatility and enhanced long-term security and importantly, allow Resonance Clinical to offer large numbers of high-value clinical assessments for drug trials. Presently, the Company's commercially available MRI phantom products, used to calibrate MRI machines, are manufactured at UWA and the molecular R&D program utilises labs at Murdoch University.

There is a strong pipeline of potential clinical trials the Company can target, and the Company is in discussions with a variety of potential collaborators and customers regarding the enhanced service offering, including existing customers already utilising the Company's services. Resonance Clinical was formally launched at the national/international AusBiotech conference on 26-28 October 2022, during which The Hon. Minister Stephen Dawson MLC, whose portfolio includes innovation and medical research, visited the Resonance Clinical booth.

To learn more about Resonance Clinical, please visit <a href="www.resonanceclinical.com">www.resonanceclinical.com</a>.



Powered by Resonance Health

#### Continued demand for clinical trial services

Resonance Health has eleven active clinical trial engagements to provide services to pharmaceutical companies undertaking clinical trials in the Company's two core disease markets of iron-overload and fatty liver disease. Since March 2022, the Company has secured its first clinical trial service contracts in each of the very large and underserviced markets of China and India and Resonance Health looks forward to providing more services in these large, new-to-the-Company, markets.

Approximately 38% of Resonance Health's revenue is derived from providing analysis and related services to pharmaceutical companies undertaking clinical trials for treatments of iron-overload and liver-fat related disorders. Resonance Health has an active business development pipeline of further clinical trial prospects that it continues to pursue, which has become even more focussed with the launch of Resonance Clinical.

Clinical trial service provision to trials aimed at new treatments for non-alcoholic steatohepatitis ("NASH"), a form of non-alcoholic fatty liver disease ("NAFLD"), has been identified as particularly prospective. Fatty-liver disease is a major global health issue, with international pharmaceutical companies seeking to develop effective drug treatments for the disease.

It is estimated that 24-30% of the global population suffers from NAFLD, roughly equating to 1.8-2.3 billion people. Of these, it is estimated that 20%, or 0.5 billion people, will also develop NASH, which can cause liver damage including fibrosis and cirrhosis and which often requires immediate medical intervention. If the prevalence of NAFLD continues to rise in line with the global obesity epidemic, it is predicted that the healthcare burden of NAFLD over the next 10 years could increase to \$1.005 trillion in the USA alone.<sup>3</sup>

<sup>&</sup>lt;sup>3</sup> Nonalcoholic fatty liver disease and cardiovascular diseases phenotypes, Glandomenico Bisaccia et al, SAGE Open Medicine Volume 8: 1-15, 21 May 2020.



#### Al and imaging R&D - LungSmart (Alert-PE) + Cystic-Fibrosis

A pre-submission meeting was held with the US Food & Drug Administration ("FDA") during the June 2022 quarter regarding the LungSmart (formerly Alert-PE) software medical device. LungSmart is an Al-assisted imaging analysis R&D project that analyses CTPA images of the lung in the case of patients with suspected pulmonary embolism ("PE"). The device has been trained on over 1,000 datasets provided via an agreement with Perth Radiological Clinic ("PRC").

The FDA has provided guidance on the next steps of development required for LungSmart, which includes using US board-certified radiologists to annotate data with region of interests ("ROIs") identifying suspected filling defects, allowing for the device to have its statistical performance measured in a future clinical study.

Resonance Health has also developed an Al-assisted cystic-fibrosis solution, with the Company continuing to seek clinical partners to use the device for investigational purposes in their assessment workflows related to persons undergoing treatment for suspected or confirmed cystic-fibrosis and/or other lung conditions. The next stage of developmental work includes exploring the addition of trapped air as a reportable metric.

#### **Molecular Medicine (ASO Project)**

The molecular medicine R&D ASO (antisense oligonucleotide) project progressed with the establishment of research collaborations with The Liver Cancer Group and the Alzheimer's Disease Research Group at Curtin University. Work on the liver cancer project relates to seeking the detection of cyclophilin-related signals in cancerous tissue versus non-cancerous tissue. Work on Alzheimer's disease relates to testing ASOs in an Alzheimer disease model. Work also continued in-house on the testing of ASOs in neuronal disease model, with the data generated potentially relevant to brain diseases such as Parkinsons, Alzheimer's, and motor neuron diseases.

#### **Molecular Medicine (Blood Marker Project)**

The Company is developing novel blood markers with the potential to provide cost-effective assessments of iron-overload and liver-health for use in countries without ready access to MRI machines. Encouragingly, preliminary analysis of a validation set of blood samples from Vietnam and Turkey appear consistent with the original findings and work continues with a scheduled completion of 31 December 2022.

#### **New Resonance Health and Resonance Clinical websites**

Two new Resonance Health websites are live: <a href="www.resonancehealth.com">www.resonancehealth.com</a> and <a href="www.resonancehealth.com">www.resonancehealth.com</a>. The first website went live on 24 July 2022 and the second very recently (post-period) went live in connection with the Resonance Clinical initiative.

#### **Financial & Operating Performance**

Demand for core-lab imaging services remains strong with approximately 2,000 patient reports generated during the quarter, contributing to positive cashflow for the quarter. Cashflow was boosted by the receipt in July of the FY22 R&D tax rebate. Cash at bank increased by \$330K to \$7.1m, with no debt across the group.

Expenditure during the quarter included \$258K in capitalised and uncapitalised R&D expenditure associated with R&D and product innovation projects. Advertising and marketing costs were marginally lower for the quarter and administration and corporate costs were marginally higher. \$28K in capitalised expenditure was recorded in relation to equipment required for the new wet-lab, part of the Resonance Clinical initiative.

Movements in exchange rates during the quarter positively impacted the Company's foreign currency cash holdings. This resulted in a positive movement in the balance of cash held during the quarter of \$194K due to this factor, as recorded in item 4.5 in the attached Appendix 4C quarterly cash flow.



An R&D tax incentive rebate of \$460K was received in July which contributed to an increase in cash at bank at the end of the quarter with cash of \$7.11M as of 30 September 2022, an increase of \$330K on cash at bank as of 30 June 2022. The Group has no debt.

With respect to item 6 of the Appendix 4C cash flow report for the quarter, payments to related parties of approximately \$100K were made during the quarter. This comprised of \$35K of remuneration paid to non-executive directors and \$65K of remuneration paid to Mr Mitchell Wells as Managing Director.

This announcement has been authorised for release in accordance with the delegated authority of the Board of Directors of Resonance Health Ltd.

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#### **About Resonance Health**

Resonance Health is an Australian healthcare technology and services company. The Company's services are used globally by clinicians in the management of human diseases and by pharmaceutical and therapeutic companies in their clinical trials. Resonance Health has gained endorsement by leading physicians worldwide for providing high quality quantitative assessments essential in managing diseases and drug development.

Resonance Health's dedication to scientific rigour and quality has enabled it to achieve regulatory clearances for a range of Software-as-Medical Devices (SaMDs) in the USA, Europe, UK, and Australia, and to proudly carry ISO 13485 certification for the design and manufacture of medical devices. Regulatory cleared SaMD products, some of which incorporate Artificial Intelligence (AI), include:

- FerriScan®, a core-lab product that provides an accurate assessment of liver iron concentration (LIC) through non-invasive MRI-based technology, for use in the assessment of individuals with iron overload conditions. Internationally recognised as the gold standard in LIC assessment.
- FerriSmart®, an Al-assisted, non-invasive MRI-based device for the automated real-time assessment of LIC in patients, calibrated against the global gold standard, FerriScan®.
- **HepaFat-Scan®**, an MRI-based solution which provides a reliable non-invasive assessment of liver-fat in liver tissue for use in the assessment of individuals with confirmed or suspected fatty-liver-disease.
- **HepaFat-Al®**, an Al-assisted, non-invasive device for the automated real-time multi-metric assessment of liver-fat in patients, for the assessment of individuals with confirmed or suspected fatty liver disease.
- LiverSmart®, an Al-assisted, non-invasive MRI-based multi-parametric device combining FerriSmart® and HepaFat-Al® into a consolidated report providing accurate assessment of LIC and liver fat.
- CardiacT2\*, the most widely accepted MRI method for assessing heart iron loading. Resonance Health offers a dual analysis of FerriScan® and CardiacT2\*. CardiacT2\* is TGA and CE Marking regulatory cleared.

The Company has a development pipeline of additional medical imaging analysis products and services, including CardiacT2\*-AI an AI tool for the automated analysis and quantification of cardiac-iron levels and LungSmart (Alert-PE™), an AI tool for the automated review of chest CT scans of patients with suspected PE.

Stakeholders, including clinicians, patients, and shareholders, are encouraged to register their interest at www.resonancehealth.com and to follow Resonance Health on Facebook, LinkedIn, and Twitter.









## **Appendix 4C**

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

### Name of entity

96 006 762 492

30 September 2022

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	1,072	1,072
1.2	Payments for		
	(a) research and development	(258)	(258)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing	(219)	(219)
	(d) leased assets		
	(e) staff costs	(646)	(646)
	(f) administration and corporate costs	(228)	(228)
1.3	Dividends received (see note 3)		
1.4	Interest received	3	3
1.5	Interest and other costs of finance paid		
1.6	Income taxes paid		
1.7	Government grants and tax incentives	460	460
1.8	Other (provide details if material)		
1.9	Net cash from / (used in) operating activities	184	184

2.	Cas	sh flows from investing activities		
2.1	Pay	ments to acquire or for:		
	(g)	entities		:
	(h)	businesses		
	(i)	property, plant and equipment	(33)	(33)
	(j)	investments		
	(k)	intellectual property	-	-
	(I)	other non-current assets		

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Cons	solidated 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 (provide details if material)		
2.6	Net cash from / (used in) investing activities	(33)	(33)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)		
3.2	Proceeds from issue of convertible debt securities		
3.3	Proceeds from exercise of options		
3.4	Transaction costs related to issues of equity securities or convertible debt securities		
3.5	Proceeds from borrowings		
3.6	Repayment of borrowings		
3.7	Transaction costs related to loans and borrowings		
3.8	Dividends paid		
3.9	Other (lease payments)	(19)	(19)
3.10	Net cash from / (used in) financing activities	(19)	(19)

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	6,783	6,783
4.2	Net cash from / (used in) operating activities (item 1.9 above)	184	184
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(33)	(33)

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Con	solidated 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)	(19)	(19)
4.5	Effect of movement in exchange rates on cash held	194	194
4.6	Cash and cash equivalents at end of period	7,109	7,109

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	6,088	5,762
5.2	Call deposits	1,021	1,021
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)	7,109	6,783

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	100	
6.2	Aggregate amount of payments to related parties and their associates included in item 2		
Note: 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.

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 qua	arter end	
7.6	Include in the box below a description of each rate, maturity date and whether it is secured a facilities have been entered into or are proposinclude a note providing details of those facilities.	or unsecured. If any add sed to be entered into af	itional financing

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	184
8.2	Cash and cash equivalents at quarter end (item 4.6)	7,109
8.3	Unused finance facilities available at quarter end (item 7.5)	
8.4	Total available funding (item 8.2 + item 8.3)	7,109
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	N/A
	item 8.1)	

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**

- 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: 31 October 2022

Authorised by: By the Board of Directors of Resonance Health Limited

#### 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.