

31 December 2022 Quarterly Update and Appendix 4C

PainChek grows customers & revenue as new global market opportunities continue to develop

PainChek Ltd (ASX: PCK) (“PainChek” or “the Company”), developer of the world’s first smart device-based pain assessment and monitoring application, is pleased to announce its quarterly activities and cashflow report (Appendix 4C) for the quarter ended 31 December 2022.

Highlights

- **Global recognised customer revenue grows to \$413,000 for the quarter and \$777,000 (unaudited) for the 6 months to December 2022, a 13% increase over previous quarter and a 127% increase half year on half year to December. Receipts from customers were \$549,000 (Q1 FY23: \$404,000). Increases in the cash receipts follow the increased commercial sales and the annual renewal dates of customers.**
- **Current annual recurring revenue (ARR) from commercial fee-paying clients is \$2.1M, a 17% increase on previous quarter and 110% over for the prior year (December 2021).**
- **Total ARR from all existing and qualified pipeline clients is \$4.4M.**
- **45,000 commercial licences are implemented globally with an additional 10,000 commercial licences to be implemented. There are an additional 30,000 beds, previously contracted under the Australian government trial, and which we are continuing to negotiate with as commercial clients.**
- **Global cumulative pain assessments on PCK database now over 2,000,000 – an 18% growth on previous quarter.**
- **US FDA regulatory process evaluation work is underway post a recent positive call with FDA – PainChek remains on track for Q4 CY23 FDA de Novo clearance for the US market.**
- **UK business development continues with 10,000 contracted RAC beds and more than 50% now implemented, and with a solid sales pipeline.**
- **North America – software integration agreed and commenced with PointClickCare providing PainChek access to more than 10,000 nursing homes and 1,000,000 residents in US/Canada. First RAC sales in Canada with Sherwood Care.**
- **Development completed of a hospital version of PainChek®, incorporating clinical workflows and integration with InterSystems TrakCare EMR. Initial pilot sites identified for UK in Q1 CY23. InterSystems manages more than one billion health records in 35 countries.**
- **Direct to consumer marketing programmes are being developed to support commercialisation of infant & children’s products.**

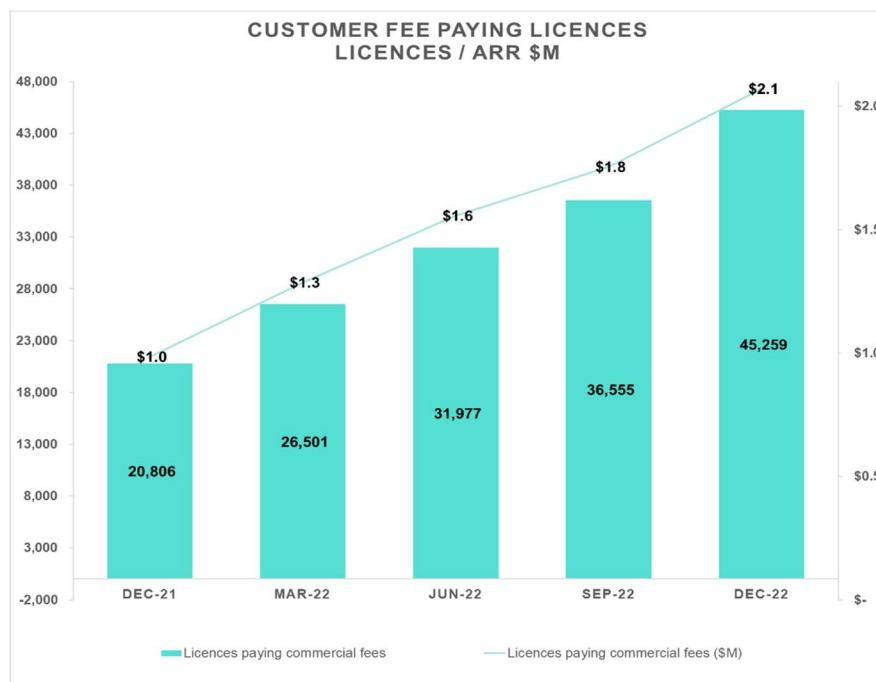
Commentary

Philip Daffas PainChek CEO said: “Philip Daffas PainChek CEO said: “The team has continued to hone its efforts in delivering the Company’s three pillar strategy and building global strategic partnerships in the process. In Aged Care we continue to successfully expand our market and broaden our sales base in Australia, UK and New Zealand with a projected \$4.4M ARR including both commercial and validated pipeline beds and now more than 2,000,000 clinical pain assessments conducted in these initial markets. We have our first commercial pilot agreements in Canada and a local US based integration agreement with PointClickCare¹ both of which provide a platform for a broader launch to more than 10,000 RAC homes in the USA post the projected FDA clearance in 2023.

We are expanding into the hospital market with our InterSystems² partnership in which we are working together to deliver a unique pain assessment capability for their global hospital clients initially in the UK and ANZ. In addition, a PainChek Infant direct to consumer market strategy is now in place to build parental demand for the technology – while continuing to generate supportive clinical evidence in readiness for a full commercial launch of PainChek® Infant in 2023.”

Global Residential Aged Care (RAC) Activity Summary

- A total of 45,000 licences are implemented under standard PainChek commercial terms increasing actual ARR to \$2.1M, a 23% increase over prior quarter and an annual growth rate of 125%.



¹ <https://www.painchek.com/latest-news/painchek-signs-marketplace-partnership-agreement-with-pointclickcare-for-usa-and-canadian-markets/>

² <https://www.intersystems.com/au/news/painchek-partners-with-intersystems-to-take-mobile-pain-assmt-app-to-hospitals-new-markets/>

- There is a total potential ARR of \$4.4M from ~99,000 licences, which includes
 - the 45,000 implemented commercial licences above
 - ~16,000 commercial licences to be implemented from current contracts
 - ~24,000 ex government trial contracted customers who were unable to undergo the process transformation by December when the grant period ended. Those customers will be looking to transition later this calendar year. The delays were typically caused due to difficulties in 2022 surrounding staff turnover, COVID lockdowns and implementing the new RAC funding model.
 - ~13,000 new customer clients pipeline, where customers have a contract being negotiated or have a short-term contract on a small number of facilities pending a wider rollout.



- PainChek utility continues to grow, with 1.97M PainChek clinical assessments conducted in aged care as of 31 December 2022, an increase of 130% over the previous year and 19% over the prior quarter, reflecting continued strong clinical utility and implementation progress.
- In December, KPMG published the National Rollout of PainChek report outlining its evaluation, including insights and key findings, from the national rollout of PainChek across residential aged care facilities. The evaluation found the national rollout delivered a range of positive impacts for aged care residents, workforce, RACFs and the aged care sector more broadly. The detailed report has been submitted privately to Federal Government, however, the summary document outlines the high-level findings and is available [here](https://www.painchek.com/resources/kpmg-report-finds-national-painchek-rollout-delivers-significant-positive-outcomes-for-the-australian-aged-care-sector/)³:

³ <https://www.painchek.com/resources/kpmg-report-finds-national-painchek-rollout-delivers-significant-positive-outcomes-for-the-australian-aged-care-sector/>

ANZ market

- In ANZ there are now 45,000 commercial beds of which 40,000 are implemented. The government funded trial has now ended, with a further 6,000 beds with customers wanting to transition onto commercial terms, and a further 23,972 (see above) customer beds who have implied they will look at implementing PainChek in 2023.
- PainChek continued its strong growth across the ANZ Aged Care market during the quarter, contracting 12 new Aged Care Providers (non-grant) covering 19 facilities. In addition to this, a significant sized Home Care agreement was secured for the use of PainChek across 585 consumers.
- RAC user training continues to be delivered remotely and the PainChek clinical team has trained over 11,000 users and “train the trainers” to assist customers in their transition to digital platforms in Australia and New Zealand.
- In the ANZ region, PainChek now has integration agreements and/or in principle agreements to integrate in place with 12 Care Management partners, covering all major CMS providers and up to 205,000 aged care beds in ANZ RAC market.
- Additional integration agreements are in place with three medication management partners, who can provide a pipeline opportunity of up to 850 residential aged care facilities in Australia, and more than 90% of all residential aged care facilities in New Zealand.

UK market update

- In the UK there are now almost 10,000 contracted beds and over 50% of these are implemented. PainChek UK had a significant representation at industry-based trade shows including Care Show, Care Roadshows (London and Cardiff), Dementia Congress, Scottish Care Conference, Nursing Homes Ireland Conference and National Care Forum CEO & Directors conference. A qualified pipeline continues to grow in the aged care, home care and hospital sectors.
- New clients include Avante Care, which has contracted to roll out PainChek® across its 10 homes and 640 beds, and National Care Consortium has agreed to adopt PainChek into three care homes across its 500-bed estate through funding provided by the Social Care Innovation Programme (SCIP). SCIP aims to enhance quality and increase sustainability in the social care sector in the region and this is the first of several homes to adopt PainChek through SCIP funding.
- Progress with Scottish Government Pilot continues as a further four sites are to be funded as part of the pilot. As part of phase 3 rollout, local health boards are looking at further expansion.
- The Gwent Regional Pilot in Wales is in progress with majority of the 1,000 funded beds taken up by providers. The results from the project will be independently validated by the Tritech Institute, a healthcare technology research venture within Hywel Dda University Health Board.

North America

- PainChek has signed agreements in Canada with Sherwood Care (102 beds) and another 153-bed provider for an initial 3-month paid pilot prior to a 12-month contract. These are implementable in Q3 FY23 post integration with PointClickCare (PCC).
- The PCC integration process continues, PainChek plans to attend the PCC US client conference in April 2023 to engage with key clients and build the US care home market entry strategy to align with FDA regulatory clearance schedule. PointClickCare Management Solution covers more than 10,000 nursing homes and 1,000,000 residents in the US and Canada. The US and Canada are priority growth markets for PainChek,

where there are in total more than 17,000 nursing homes providing long term care across more than 1,900,000 beds.

- PainChek has regulatory clearance in Canada. US FDA de Novo regulatory clearance is currently projected for Q4 Calendar 2023.

US FDA (Food and Drug Administration)

- PainChek has held positive conference calls with the FDA, confirming the clinical trial process. Given this dialog and the elements of the trial approved, the Company remains on target for a Q4 CY23 US deNovo regulatory clearance for the adult technology.
- Key developments with the clinical trial include:
 - Healthcare Human Factors have completed Human Factor Validation Testing involving a total of 60 doctors, nurses and therapists in the US, as a prerequisite for PainChek's psychometric evaluation (validation and reproducibility and repeatability) studies in the US.
 - The protocol with the psychometric evaluation studies have been reviewed by the FDA who has given PainChek the go ahead to conduct them.
 - Donawa Lifesciences, the Clinical Research Organisation appointed in US to conduct PainChek's psychometric evaluation studies, have commenced recruitment of the local US clinical sites to complete the studies in time.

Japan

- In order to better access the Japan market PainChek has engaged a Japan-based Business Development consultant to represent it to the PDMA (Pharmaceuticals and Medical Devices Agency) for the regulatory clearance process, as well as to open channels to other potential Japanese clients and partners.
- PainChek's participation in the JETRO Business Connect program has resulted in ongoing engagement with several Japanese Hospitals and Universities.

Integration partners

PainChek's technology partners continue to grow and includes electronic Medication Administration Records (eMAR) and Medication Management tools, Electronic Health Records (EHR) systems and others. These partners directly service Aged Care, Community and Disability Care, Pharmacy and Hospitals with client bases around the globe.

With 30+ sector partners, and growing, PainChek's partnerships not only adds value for clients, but meaningful sales/marketing opportunities, and access to trusted collaborators to provide support as the Company continues to grow and diversify.

PAINCHEK'S EXISTING EMR & MEDICATION MANAGEMENT AND INTEGRATION PARTNERS

PainChek integrates and works with aged care management and medication management systems covering more than 180,000 aged care beds in Australia, 25,000 beds in New Zealand, 195,000 beds in the UK & Ireland, and 1,000,000 beds in North America

Integration with Medication Management partners support the drive to better care delivery and eliminating duplication of effort and optimising medication management



8 | PainChek

Hospitals

- InterSystems and PainChek continue to work together to bring the PainChek technology into the global hospital market and to InterSystems global hospital client base. The PainChek® Adult application has been developed and integrated with the InterSystems TrakCare EMR (Electronic Medical Record) platform to provide a novel point of care hospital pain assessment and pain management solution.
- InterSystems has more than one billion health records worldwide being managed using InterSystems technology in over 25 countries. InterSystems has demonstrated InterSystems IRIS for health integrating PainChek in the cloud to a number of hospitals using TrakCare.
- The collaborative technology solution provides improved clinical workflows, reports and care processes for the TrakCare EMR (Electronic Medical Records), based on PainChek® data, which will further support the clinical value of the PainChek® application in the hospital environment.
- The two Companies are working with a large UK based hospital network for an initial pilot implementation, projected for Q1 CY23.

Children's and Infant App

- PainChek is embarking on a direct to consumer (parental) marketing programme in Australia to build end consumer awareness and refine the PainChek Infant marketing mix prior to a broader direct to consumer market release projected for Q2 CY23.
- PainChek is compiling additional clinical utility evidence data to support the commercial use of the Infant App:

- The Royal Children's Hospital in Melbourne and Los Angeles Children's hospital continue to recruit patients and generate utility data for validity and reliability of the application for the assessment of procedural pain amongst infants in the Emergency Department.
- Recruitment continues in Europe in an infant circumcision project.

Research

- Two research papers were accepted ready for publication:
 - 'Assessing pain using facial recognition software among Aboriginal aged care residents with cognitive impairment: a retrospective cohort study' – Australasian Journal of Ageing – Chris Rissel, Nicole Tate, Leigh Moore, Narelle Campbell, Jeff Hughes, Catherine Smith, Anthony Lew-Fatt, Shahid Ullah.
 - 'The clinical suitability of an artificial intelligence enabled pain assessment tool for use in infants: a feasibility and usability evaluation' – Journal of Medical and Internet Research – Jeffery Hughes, Paolo Chivers, Kreshnik Hoti.

Technology Development & Patents

- The planned PainChek technology upgrade commenced at the start of Q2 FY23 and is on track for completion in July 2023. This upgrade expands PainChek's capability to not only service mobile platforms but also embedded computer platforms and broaden access to virtual care usage.
- Patents granted to date include USA, Japan and China with EU still in progress, each under relevant local patent rules and regulations. The Australian patent application has not been granted and the Company is currently considering whether to appeal this decision. However, management does not see this as material as PainChek has already established a market leadership position in Australia.

Corporate

- The AGM was held on 23 November 2022 and the results were published on the ASX.
- In December PainChek announced Lisa Dadswell was appointed Company Secretary.
- The recognised revenue from customers was \$413,000 (unaudited) for the quarter and \$777,000 (unaudited) for the 6 months to December 2022, a 13% increase over previous quarter and a 127% increase half year on half year to December.

Cashflow

- Receipts from customers were \$549,000 (Q1 FY23: \$404,000). Increases in the cash receipts are partly due to the increased commercial sales and also the annual renewal dates of customers.
- Research and development payments were \$720,000 (Q1: \$419,000). The increase in payments is from the FDA clinical trials and also the core technology upgrade that commenced at the end of Q1
- Advertising and Marketing payments increase to \$258,000 (Q1: \$186,000). There was an increase in UK marketing and telemarketing.
- Staff Costs payments were \$1,080,000 (Q1: \$1,108,000).

- Administration and Corporate costs increased to \$669,000 (Q4: \$599,000). There were increases in IT costs associated with improved cyber security services.
- In accordance with ASX Listing Rule 4.7C.3, the amount of \$112,500 stated in section 6.1 of the Appendix 4C paid to related parties and their associates related to director fees and salaries for the quarter. The company made payments to directors during the period of \$112,500: \$50,000 to non-executive and \$62,500 to executive directors.

¹ <https://dcricri.org/coa-aptic/>

This announcement has been approved for release by the Board.

For more information:

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About PainChek®

PainChek® Ltd is an Australian based company that develops pain assessment technologies.

Pain often goes unrecognised and under-treated in people with communication difficulties. PainChek Universal is a clinically validated smartdevice-based medical device that enables best practice pain assessment for all people, everywhere.

PainChek Universal is a complete point-of-care solution that combines the existing PainChek® App with the Numerical Rating Scale (NRS). This enables best-practice pain management for all residents living with pain in any environment — from those who cannot verbalise pain to those who can, and those who fluctuate between the two.

The PainChek® App uses artificial intelligence and facial recognition to detect pain in those who cannot self-report. This gives a voice to those who cannot verbalise pain, whilst also driving objectivity and consistency in all assessments. For those who can self-report, PainChek Universal also includes access to the Numerical Rating Scale, a well-established standard used to document pain levels amongst these individuals. PainChek Universal also supports pain assessment using both tools at the point of care, for those people whose ability to communicate fluctuates.

PainChek® is being rolled out globally in two phases: first, PainChek® for adults who are unable to effectively verbalise their pain such as people with dementia, and second, PainChek® for infants who have not yet learnt to speak. Both the adult and infant products have received regulatory clearance in numerous markets including Australia, Europe, UK, NZ, Singapore and Canada.

To find out more, visit www.painchek.com

+Rule 4.7B

Appendix 4C

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

Name of entity		
PAINCHEK LTD		
ABN	Quarter ended ("current quarter")	
21146035127	31/12/2022	

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
1.0 Cash flows from operating activities		
1.1 Receipts from customers	549	953
1.2 Payments for		
(a) research and development	(720)	(1,139)
(b) product manufacturing and operating costs		
(c) advertising and marketing	(258)	(444)
(d) leased assets		
(e) staff costs	(1,080)	(2,187)
(f) administration and corporate costs	(669)	(1,268)
1.3 Dividends received (see note 3)		
1.4 Interest received	0	0
1.5 Interest and other costs of finance paid		
1.6 Income taxes paid		
1.7 Government grants and tax incentives	0	20
1.8 Other (GST)	31	(10)
1.9 Net cash from / (used in) operating activities	(2,147)	(4,076)

2.0 Cash flows from investing activities		
2.1 Payments to acquire:		
(a) entities		
(b) businesses		
(c) property, plant and equipment	(6)	(14)
(d) investments		
(e) intellectual property		
(f) other non-current assets		
2.2 Proceeds from disposal of:		
(a) entities		
(b) businesses		
(c) property, plant and equipment	0	1
(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	(6)	(12)

3.0 Cash flows from financing activities		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	0	2,696
3.2 Proceeds from issue of convertible debt securities		

3.3	Proceeds from exercise of options	0	0
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 (provide details if material)		
3.10	Net cash from / (used in) financing activities	0	2,696

4.0	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	6,927	6,141
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,147)	(4,076)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(6)	(12)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	0	2,696
4.5	Effect of movement in exchange rates on cash held	8	32
4.6	Cash and cash equivalents at end of period	4,781	4,781

5.0	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	4,781	6,141
5.2	Call deposits	0	0
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)	4,781	6,141

6.0 Payments to related entities of the entity and their associates

- 6.1 Aggregate amount of payments to related parties and their associates included in item 1
- 6.2 Aggregate amount of payments to related parties and their associates included in item 2

**Current quarter
\$A'000**

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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.

7.0 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 position

- 7.1 Loan facilities
- 7.2 Credit standby arrangements
- 7.3 Other (please specify)
- 7.4 **Total financing facilities**

Total facility amount at quarter end	Amount drawn at quarter end
\$A'000	\$A'000

7.5 Unused financing facilities available at quarter end

- 7.6 Include in the below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional 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.

8.0	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(2,147)
8.2	Cash and cash equivalents at quarter end (item 4.6)	4,781
8.3	Unused finance facilities available at quarter end (item 7.5)	0
8.4	Total available funding (Item 8.2 + Item 8.3)	4,781
8.5	Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	2.2
<p><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></p>		
8.6	<p>If Item 8.5 is less than 2 quarters, please provide answers to the following questions:</p> <p>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?</p> <div style="border: 1px solid black; padding: 5px; margin: 5px 0;"> <p>Answer: Yes</p> </div> <p>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?</p> <div style="border: 1px solid black; padding: 5px; margin: 5px 0;"> <p>Answer: The company has successfully raised funds from investors and current shareholders in the past, and expects this support to continue going forward.</p> </div> <p>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?</p> <div style="border: 1px solid black; padding: 5px; margin: 5px 0;"> <p>Answer: Yes. The company has sufficient funds to meet the operating activities until Q1 FY24. There are currently 2 significant projects, being the FDA regulatory application and the core technology upgrade. The committed expenditure for these will significantly decline at the end of FY23.</p> </div> <p><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></p>	

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: 31/01/2023

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.