ASX Release
28 October 2021

ASX code: PIQ

Quarterly Activities Report

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), a medical technology company at the forefront of precision medicine and predictive diagnostics, is pleased to provide the following update on its business activities for the three months to 30 September 2021 and subsequent to the period end.

This has been a highly significant quarter for the Company, with four pivotal milestones achieved:

- **Diabetes treatment lowers PromarkerD risk score (Janssen Stage 2 results):** Proteomics International has previously published the results of several studies showing that its PromarkerD test can predict future kidney function decline in patients with type 2 diabetes and no existing diabetic kidney disease (DKD). Now, for the first time, strong positive results from a study with US pharmaceutical company Janssen have shown that the gliflozin class drugs offer a new treatment option for these at-risk patients.
- **Northern Hemisphere manufacturers engaged for PromarkerD immunoassay test:** Proteomics International has implemented global manufacturing standards for the production of the PromarkerD assay and engaged manufacturing specialists Biotem and Abcam to enable large scale production of the test as global sales grow.
- **Clinical utility study demonstrates benefit of PromarkerD testing:** Results presented to a conference of US insurance companies and payors have demonstrated PromarkerD's appeal to clinicians in the management of diabetic kidney disease. This clinical utility study will also form a valuable part of the information dossier to support Proteomics International's application for a unique US reimbursement code for PromarkerD.
- **Promarker diagnostics pipeline advances - Collaboration to develop test for endometriosis:** Proteomics International's rich pipeline of new intellectual property in development was exemplified by a partnership with the University of Melbourne and the Royal Women's Hospital to advance the Company's potential new blood test for endometriosis. Proteomics International's portfolio of other diagnostic tests in development also continues to mature.

Proteomics International continues to see growth opportunities on multiple fronts across its portfolio of activities and includes its 2021-22 outlook for several major areas below.

OPERATIONAL HIGHLIGHTS

Proteomics International's activities fall into three key areas:

(i) commercialisation of PromarkerD, the predictive test for diabetic kidney disease (DKD)
(ii) R&D for new diagnostic tests using the Promarker™ pipeline
(iii) analytical services on a commercial basis

Commercialisation of PromarkerD

Diabetes treatment lowers PromarkerD risk score (Janssen Stage 2 Collaboration)

[ASX: 16 July, 11 August] A collaborative study conducted by Proteomics International and Janssen Research & Development found a significant reduction in the PromarkerD risk scores of patients with type 2 diabetes taking canagliflozin, an SGLT2-inhibitor diabetes drug.

The study was the second stage of the collaboration between Proteomics International and Janssen [ASX: 31 Mar 2020; 15 Jun 2020], in which the companies examined the association between canagliflozin, an approved diabetes therapy with additional renal benefits, and change in PromarkerD score. As reported in the June quarterly update the research measured PromarkerD scores in blood samples from more than 2,000 patients in the completed CANVAS clinical trial.

The results showed the average PromarkerD risk score of patients taking canagliflozin dropped during the three-year trial, while the average risk score of patients taking a placebo rose. The biggest reductions were seen in the patients classified by PromarkerD at the start of the trial as at high risk of developing DKD. The findings were presented at the Australasian Diabetes Congress 11-13 August 2021.

The results confirm that this SGLT2 inhibitor class of diabetes drug [see Annual Report 2021 - Technology Snapshot: New Therapeutics for DKD - Gliflozins] improve the renal risk profile of diabetes patients identified by PromarkerD as being at high risk of DKD, giving these patients the chance to reduce their risk of developing symptoms in the future. The results also suggest rationalised treatment options would be appropriate in patients identified by PromarkerD as being at low-risk of developing DKD.

These positive results build on the Janssen Stage 1 results from 2020, and form an important part of the information pack provided for licensing discussions and for interactions with regulatory agencies around the world.

Northern Hemisphere manufacturers engaged for PromarkerD immunoassay test

[ASX: 22 July; 28 July; 12 August] Proteomics International has contracted European immunoassay specialist Biotem to manufacture PromarkerD test kits. As reported in the June quarterly update, the Company also engaged global life science company Abcam plc to produce specialist reagents for the immunoassay version of the test.

The milestone agreements will see Biotem, an ISO 13485 certified manufacturer, produce the PromarkerD immunoassay kit using specialist reagents (antibodies and recombinant proteins) produced by Abcam. These agreements strengthen the Company's supply chain and enable scale-up of PromarkerD production as Proteomics International targets sales globally. The process of transferring the manufacturing process to Biotem (currently PromarkerD is manufactured in Australia) has commenced and is scheduled to be completed in Q1 CY22.

Clinical utility study demonstrates benefit of PromarkerD testing

[ASX: 18 October] A clinical utility study has demonstrated that PromarkerD can help inform doctors' treatment decisions and improve clinical outcomes for patients with type 2 diabetes. The US-based web survey of 400 primary care physicians and endocrinologists found the PromarkerD test significantly impacted physicians' prescribing and monitoring decisions.

The analysis showed that PromarkerD tests were more important to physicians than the current standard-of-care tests — estimated glomerular filtration rate (eGFR) and albumin-to-creatinine ratio (ACR). More than three-quarters of physicians reported they were very or extremely likely to use PromarkerD in the future.

Senior author of the study Dr Alexander Turchin, an endocrinologist at Boston's Brigham and Women's Hospital, said "*When presented with moderate or high-risk PromarkerD results, physicians were more likely to implement renoprotective changes—such as increasing monitoring frequency,*

prescribing SGLT2 inhibitors or replacing ibuprofen—than if they did not have the PromarkerD test results. These changes can help avoid end-stage interventions such as dialysis and kidney transplant. In contrast, when presented with low-risk PromarkerD results, the likelihood of aggressive treatment and health care resource utilisation reduced."

The results were presented at AMCP Nexus, a managed-care pharmacy conference 18-21 October in Denver, USA, in association with Boston Healthcare Associates and specialist US endocrinologists.

PromarkerD - Outlook 2021-22

US Reimbursement Code

[ASX: AR 2021; 18 October] The clinical utility study demonstrating the beneficial impact of PromarkerD testing on patient treatment decisions by physicians provided the second of two essential components for the Company's dossier to support an application for a US reimbursement code. This study, together with the previous studies showing the economic health benefit of PromarkerD testing [ASX: 2 July] provide strong evidence for the adoption of PromarkerD testing internationally.

The economic health benefit study demonstrated the potential cost savings to the US Healthcare system if PromarkerD was adopted, compared to the current standard of care. That study found that instigating PromarkerD testing produced savings primarily from slowing the progression of DKD and delaying or preventing dialysis and kidney transplants against the costs associated with increased testing and the use of preventative medications.

The clinical utility study and the economic health benefit study will support the Company's application for a reimbursement code, which will facilitate the reimbursement of the PromarkerD test by insurance companies and other payors in the US. This is important because it means that the cost of the test may be covered by insurers or other payors, instead of the patient.

New reimbursement codes are approved quarterly by the American Medical Association (AMA) and its Current Procedural Terminology (CPT) Editorial Panel, and follow assessment of the economic health benefit and clinical utility of a new test. A CPT Proprietary Laboratory Analyses (PLA) code uniquely identifies a test for the laboratory and the payors. The Company will seek a unique code for PromarkerD once the test is available in the US, via the Laboratory Developed Test (LDT) pathway in conjunction with partnering/licensing with a US based diagnostics laboratory. Prior to such granting of a unique reimbursement code the Company intends to follow standard procedure and use a miscellaneous reimbursement code (the already identified miscellaneous code will allow a price of no less than the previously stated $150 per test).

Laboratory partners in the US, EU and Rest-of-World markets

Proteomics International is in ongoing discussions with potential US laboratory partners to provide PromarkerD to diabetes patients. There are approximately 31 million at-risk diabetes patients in the US[1] , where DKD is the 16th leading cause of death, accounting for 40,000 deaths per year[2].

The provision of the PromarkerD test in Italy via the distribution agreement with Medical Horizons [ASX: 16 October 2020] has been disrupted by the Covid-19 shutdown of routine operations in that country. Consequently, the roll-out is approximately nine months behind schedule. Nonetheless, Italy, with 3.7 million people with diabetes[1], remains a 'beachhead' for the launch of PromarkerD in Europe. The Company is currently working closely with selected major hospitals to complete the set-up and onboarding of PromarkerD in these facilities and achieve first commercial sales of PromarkerD. Given the major obstacles presented by Covid-19 are largely out of the way, the Company is confident of achieving sales in this current (December) quarter.

The second distribution agreement for the PromarkerD immunoassay kit, which was with Zotal Ltd for Israel [ASX: 12 November 2020], has also been adversely affected by the Covid-19 pandemic. To launch PromarkerD in Israel Proteomics International will now wait for the completion of the

1 International Diabetes Federation 2019

2 The State of US Health, 1990-2016

transfer to ISO13485 kit manufacturing to enable easier registration of the test with the Israeli Ministry of Health.

Proteomics International continues to target new markets for PromarkerD across multiple regions and is in advanced discussions with several major parties in Europe and other global jurisdictions.

Regulatory submissions and approvals

Proteomics International has been advised that its 513(g) submission to the United States Food and Drug Administration (FDA) is now under review. This follows a significant procedural delay due to the Covid-19 pandemic. The application will allow Proteomics International to determine the best regulatory path for PromarkerD—either the De Novo Classification or 510(k) route. The Company is preparing to file a full application once the required pathway for PromarkerD is determined. The route to market in the US remains the LDT (laboratory developed test) path through CLIA (Clinical Laboratory Improvement Amendments) certified labs, which allows sales to commence prior to any FDA approval.

PromarkerD is currently CE Mark registered in the European Union. In May 2022 new EU regulations (IVDR 2017/746) are due to come into force, and Proteomics International is currently finalising documents for a submission to update its registration in accordance with these new regulations and anticipates no issues with maintaining CE Mark registration. In parallel, Proteomics International is also preparing documents to seek regulatory approval of the PromarkerD test by the Australian Therapeutic Goods Administration.

Key Opinion Leader (KOL) engagement & Conference presentations

As exemplified by the above clinical utility study and its conference presentation, Proteomics International continues to engage with Key Opinion Leaders (KOL's) and industry representatives directly and by conference attendance. The Company believes that this strategy, and the accompanying peer review process, provides the best long term route to broad recognition and adoption of the PromarkerD test in global markets. Proteomics International looks forward to providing further updates on its relationships with KOLs in the coming months.

Further information about PromarkerD is available through the web portal (www.PromarkerD.com).

To visit the PromarkerD virtual product display please see: www.PromarkerD.com/product

Diagnostics

Proteomics International, University of Melbourne and Royal Women's Hospital collaborate to develop test for endometriosis

[ASX: 4 August] Proteomics International signed a research agreement with the University of Melbourne and the Royal Women's Hospital to collaborate to develop a world first, non-invasive test for endometriosis. The partnership aims to develop the world's first blood test for the painful condition, which affects one in nine women and costs Australia $9.7 billion each year [see AR 2021 - Window on the Science: Endometriosis].

The collaboration builds on a Proteomics International study that identified protein biomarkers in the blood that could be used to test for endometriosis [ASX: 23 March 2020]. Key to the research is a world-leading endometriosis database managed by the Royal Women's, which contains anonymous biological samples and survey information from more than 900 women with endometriosis. It is the largest and most in-depth endometriosis database and tissue bank in Australia, and is being used to validate the panel of biomarkers discovered by Proteomics International. The laboratory analysis has commenced and preliminary results are expected in Q1 CY22.

Managing Director Dr Richard Lipscombe was interviewed by ABC radio in relation to this exciting collaboration and a link to the interview is provided on the Company's website.

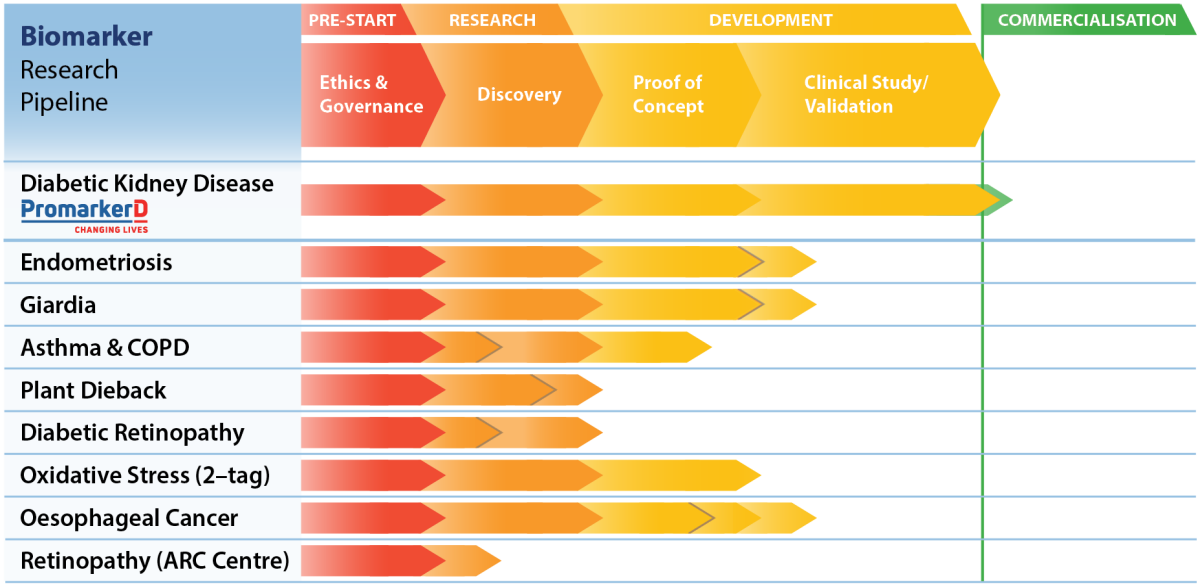
Diagnostics - Outlook 2021-22

The Promarker pipeline

[ASX: 30 August] Proteomics International is beginning to reap the benefits of the Company's strategy to expand its diagnostic development pipeline last year. Several biomarker research programs have progressed, with four now at the 'clinical validation' stage (endometriosis, *Giardia*, oxidative stress and oesophageal cancer) and three at or near completion of 'proof of concept' (asthma/COPD, diabetic retinopathy, plant dieback).

All programs to develop new diagnostic tests are in areas of unmet need, and each has the potential to deliver significant value for Proteomics International. The Company looks forward to providing project specific updates during the coming quarter.

DIAGNOSTICS RESEARCH AND DEVELOPMENT – THE PROMARKER™ PIPELINE



The Promarker™ R&D pipeline and typical timeline is as follows: Ethics & governance approval (3 months), Discovery (6 months), Proof of concept (6 months), Clinical studies/Validation (12 months) (Grey lines indicate project progress as at the Company's 2020 Annual Report).

FINANCIAL AND CORPORATE HIGHLIGHTS

Proteomics International's business model is to continue the commercialisation of PromarkerD whilst using its Promarker™ technology platform to create a pipeline of novel diagnostic tests, and offset the cash burn from R&D and product development through its analytical services revenue, coupled with the R&D tax incentive rebate. This diversified model has shown its strength in the current economic climate and enables the group to continue to make optimum use of its resources.

Revenue & Expenditure

Proteomics International achieved receipts from customers for the September quarter of $373,000 (June quarter: $395,000).

Receipts continue to be driven by revenue from analytical services. In particular, the Company has observed a significant increase in demand for its pharmacokinetic testing services (related to clinical trials), and renewed interest in biosimilars testing - an area that was negatively affected in FY21 by the Covid-19 shutdowns in markets such as India. Initial revenues from the PromarkerD test are now expected to commence in the December quarter.

The net operating cash outflow for the September quarter was $1.16 million (June quarter: $1.44 million). Expenditure was in line with budget and centred on the following areas:

- Business development and commercialisation costs for the roll-out of PromarkerD
- Manufacturing costs for the PromarkerD immunoassay kit
- Regulatory and reimbursement activities to support PromarkerD commercialisation
- R&D for projects in the Promarker™ diagnostics pipeline

ASX Listing Rule 4.7C
Payments at item 6.1 of the Appendix 4C of $120,000 relate to normal remuneration of Executive and Non-Executive Directors.

Cash position
At 30 September 2021 the Company had cash reserves of $4.4 million (June $5.6 million). These reserves will be strengthened by an estimated R&D tax incentive rebate of $1.2 million expected to be received in the December quarter. The Company is confident that its diversified business model places it in a strong financial position to fund its objectives for CY22.

Board Renewal
[ASX: 26 October] Proteomics International announced that its Chairman Terry Sweet will retire at its 2021 AGM. Mr Sweet was instrumental in taking Proteomics International Laboratories Ltd through its initial public listing as an R&D focused $10 million dollar enterprise to the commercially driven $100 million (circa) business it is today. The Board has commenced the renewal process and intends to appoint new directors in due course.

Annual General Meeting
The 2021 AGM will be held on 25 November and the Company looks forward to providing a further update on its activities at that time.

Authorised by the Board Proteomics International Laboratories Ltd (ASX.PIQ).

ENDS

About Proteomics International Laboratories (PILL) (www.proteomicsinternational.com)
Proteomics International (Perth, Western Australia) is a wholly owned subsidiary and trading name of PILL (ASX: PIQ), a medical technology company at the forefront of predictive diagnostics and bio-analytical services. The Company specialises in the area of proteomics – the industrial scale study of the structure and function of proteins. Proteomics International's mission is to improve the quality of lives by the creation and application of innovative tools that enable the improved treatment of disease.

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Appendix 4C

Quarterly report for entities subject to Listing Rule 4.7B

Name of entity

Proteomics International Laboratories Ltd

ABN	**Quarter ending ("current quarter")**
78 169 979 971	**30 September 2021**

Consolidated statement of cash flows		**Current Quarter $A'000**	**Year to date $A'000**
1.	**Cash flows related to operating activities**		
1.1	Receipts from Customers	373	373
1.2	Payments for		
	(a) research & development	(883)	(883)
	(b) product manufacturing & operating costs	(58)	(58)
	(c) advertising & marketing	(42)	(42)
	(d) leased assets	0	0
	(e) staff costs	(274)	(274)
	(f) administration & corporate costs	(278)	(278)
1.3	Dividends received (see note 3)	0	0
1.4	Interest received	2	2
1.5	Interest & other costs of finance paid	0	0
1.6	Income taxes paid	0	0
1.7	Government grants & tax incentives	0	0
1.8	Other (Deferred Grant Income)	0	0
1.9	**Net cash from / (used in) operating activities**	**(1,160)**	**(1,160)**

2.	**Cash flows related to investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	0	0
	(b) businesses (see item 10)	0	0
	(c) property, plant & equipment	(48)	(48)
	(d) investments	0	0
	(e) intellectual property	0	0
	(f) other non-current assets	0	0
2.2	Proceeds from disposal of:		0
	(a) entities	0	0
	(b) businesses (see item 10)	0	0
	(c) property, plant & equipment	0	0
	(d) investments	0	0
	(e) intellectual property	0	0
	(f) other non-current assets	0	0
2.3	Cash flows from loans to other entities	0	0
2.4	Dividends received (see note 3)	0	0
2.5	Other (provide details if material)		
2.6	**Net cash from / (used in) investing activities**	**(48)**	**(48)**

Consolidated statement of cash flows		Current Quarter $A'000	Year to date $A'000
3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	0	0
3.2	Proceeds from issue of convertible debt securities	0	0
3.3	Proceeds from exercise of options	24	24
3.4	Transaction costs related to issues of equity securities or convertible debt securities	0 0	0 0
3.5	Proceeds from borrowings	0	0
3.6	Repayment of borrowings	0	0
3.7	Transaction costs related to loans & borrowings	0	0
3.8	Dividends paid	0	0
3.9	Other (provide details if material)	0	0
3.10	**Net cash from / (used in) financing activities**	**24**	**24**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash & cash equivalents at beginning of period	5,604	5,604
4.2	Net cash from / (used in) operating activities (see 1.9 above)	(1,160)	(1,160)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(48)	(48)
4.4	Net cash from / (used in financing activities (item 3.10 above)	24	24
4.5	Effect of movement in exchange rates on cash held	0	0
4.6	**Cash & cash equivalents at end of quarter**	**4,420**	**4,420**

5.	**Reconciliation of cash & 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 balance	870	554
5.2	Cash deposits	3,550	5,050
5.3	Bank overdrafts	0	0
5.4	Other (provide details)	0	0
5.5	**Cash & cash equivalents at end of quarter (should equal item 4.6 above)**	**4,420**	**5,604**

6.0	**Payments to related parties of the entity & their associates**	**Current Quarter $A,000**
6.1	Aggregate amount of payments to related parties and their associates included in item 1	120
6.2	Aggregate amount of payments to related parties and their associates included in item 2	0

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

Payments at 6.1 relate to normal remuneration of Non-Executive and Executive Directors

7.	**Financing facilities available** *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	0	0
7.2	Credit standby arrangements	0	0
7.3	Other(please specify)	0	0
7.4	**Total financing facilities**	**0**	**0**
7.5	**Unused financing facilities available at quarter end**		**0**

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.

N/A

8.	**Estimated cash outflows for next quarter**	**$A'000**
8.1	Net cash from / (used in) operating activities (see 1.9 above)	(1,160)
8.2	Cash & cash equivalents at quarter end (Item 4.6)	4,420
8.3	Unused financing facilities available at quarter end (item 7.5)	0
8.4	Total available funding (Item 8.2 + Item 8.3)	4,420
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	**3.8***

**Estimated R&D tax incentive rebate of $1.2m expected to be received in the December quarter.*

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:

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:

8.6.3 Does the entity expect to be able to continue its operations and to meet it's business objectives and, if so, on what basis?

Answer:

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 abd 8.6.3 above must be answered.

Compliance Statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 28th October 2021

Authorised by: The Board
(Name of body or officer authorising release - see note 4)

Notes

1. The quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entities acitivities 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 proisions of. AASB 107: Statement of Cash Flows apply to this report. If this quarterly 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 - e.g. 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.