

#### **ASX ANNOUNCEMENT**

# **Lumos Diagnostics Quarterly Activity Statement and Cash Flow Report**

# **Key Highlights from the Fourth Quarter of Financial Year 2025**

- FY25 revenue of US\$12.4 million (unaudited), up 12% compared to FY24 of US\$11.1 million.
- **Revenue of US\$2.6 million for the quarter**, down 26% compared to the previous quarter due to end of U.S. flu season.
- Q4 Product revenue was up 7% on the pcp and Services revenue was down 43% on the pcp.
- **FebriDx CLIA Waiver Study approaches completion** with 105 of the targeted 120 positive bacterial patients enrolled. United States (U.S.) Food and Drug Administration (FDA) application anticipated within three months.
- Lumos U.S. Medicare payor coverage in place for FebriDx®, representing 20%-24% of the reimbursement payor mix, following the onboarding of six of the seven Medicare Administrative Contractor's (MAC's).
- Hologic fFN project continues to progress with Phase 2 work completed, and an additional Statement of Works (SOW) for this phase requested by Hologic, with work underway.
- Cash balance of US\$2.0 million as at 30 June 2025.
- Operating cash outflow for Q4 was US\$1.7 million.
- Post Reporting Date: Lumos signs US\$317 / A\$487<sup>1</sup> million exclusive distribution agreement for FebriDx® in the U.S. with PHASE Scientific, representing one of the largest distribution agreements by an Australian point-of-care diagnostics company.
- Lumos also secured a binding term sheet for a discretionary A\$5.0 million loan facility, to support working capital, past the anticipated granting of CLIA waiver.

All amounts are in USD, the Company's reporting currency, unless otherwise stated.

**MELBOURNE, Australia (21 July 2025)** – Lumos Diagnostics (ASX: LDX), ("Lumos" or the "Company") a leader in rapid point-of-care diagnostic technologies, is pleased to release its Quarterly Activity Statement and Appendix 4C Quarterly Cash Flow Report for the fourth quarter of FY25 (Q4 FY25 / the three months ended 30 June 2025).

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<sup>&</sup>lt;sup>1</sup> AUDUSD = 0.651 as at 15 July 2025

#### **Operational Update**

Lumos recorded unaudited revenue of US\$2.6 million for the quarter ended 30 June 2025, down 26% compared to Q3 FY25.

Revenue generated during the quarter from the Services business was US\$2.3 million versus US\$2.8 million in Q3. The Hologic fFN Development Agreement and the Intellectual Property licensing revenue associated with the Hologic IP Agreement continued to generate the majority of revenue. The decline on the previous quarter was primarily due to the reduced monthly revenue recognition rate of the Intellectual Property Agreement (US\$10.0 million upfront payment), from US\$0.37 million to US\$0.27 million per month, and a reduction in the revenue recognized from the Development Agreement, from US\$0.17 million, per month to US\$0.12 million, per month. This was due to the estimated timeline for the project being extended by 3 months.

Revenue from the Products business during the quarter was US\$0.3 million, versus US\$0.7 million in Q3 FY25, due to the end of U.S. flu season, but up 7% on the Q4 FY24 revenue. Increasing adoption of FebriDx® across the U.S. resulted in revenue growth of 522% on the pcp for this product. During the quarter, sales of ViraDx® declined due to the end of the flu season and increased competition from international suppliers. From June 2025, Lumos commenced distributing CorDx Tyfast Flu A/B & Covid-19 multiplex test, as an alternative for ViraDx®, at a more competitive price point.

# **Development Services and Contract Manufacturing Division**

Lumos generated US\$2.3 million from the provision of diagnostic test and custom reader development services, contract manufacturing and IP license revenue during the June quarter. Development services included ongoing project work for Hologic, Burnet Diagnostics Initiative, Huvepharma, TeleMedVet and other customers.

#### Hologic

On 11 January 2024, Lumos announced an IP and Development agreement with Hologic, a leading global women's health provider, to develop the next generation of Hologic's on-market fFN diagnostic product for pre-term birth, for which Hologic is the only global manufacturer. A key focus of the development program is to adapt the test for use on the Lumos proprietary reader platform and provide improved connectivity options.

On 3 March 2025, the project's SOW was expanded, relating to the delivery of the system prototype (refer to ASX announcement for more detail). The expanded program is estimated to generate additional fee revenue for Lumos of between US\$0.6 - US\$0.8 million, to be invoiced as the work is completed.

Including the extended SOW, the body of work under the Development Agreement is being conducted across three phases, providing total milestone payments of US\$5.3 million to US\$5.5 million, structured as follows:

- Phase 1 Product Definition and Planning: define the parameters for the product and establish a project plan - US\$0.4 million - completed as announced on 6 May 2024. Payment has been received for this phase;
- Phase 2 Assay Feasibility: conduct work to demonstrate the assay can detect the biomarkers US\$0.6 million work on the first milestone of this phase has been completed, comprising US\$0.3 million payment, as announced on 20 September 2024, and payment has been received. Work on the second and final milestone for this phase, worth \$0.3 million, is nearing completion. Hologic has asked for additional studies to complete the assay feasibility phase. Lumos is currently scoping this piece of work and plans to provide Hologic with a SOW shortly and will be paid on a time and materials basis. The extra assay SOW is estimated to take around 3 months.
- Phase 3 System Prototype Delivery: deliver a working prototype of the system US\$4.3 million to
  US\$4.5 million the first and second of the six Phase 3 milestones are in progress. Whilst Lumos
  completes the additional SOW on assay feasibility, work on these Phase 3 milestones is likely to be
  delayed, so the estimated timeline for the project has been pushed out by a further three months
  to March 2026.

#### **Products Division**

We provide a summary of the following product updates below.

# FebriDx®

FebriDx® is Lumos' unique, rapid point of care test that helps clinicians differentiate between bacterial and non-bacterial acute respiratory infections through a simple fingerstick blood sample in around 10 minutes. To date, Lumos has received regulatory registrations for the use of FebriDx® in the U.S., UK, Europe, Canada, UAE and Australia. During the quarter, FebriDx® achieved a number of pivotal milestones.

Post Reporting Date: On 16 July, Lumos entered into one of the largest distribution agreements signed by an Australian point-of-care diagnostics company. The six-year exclusive agreement provides PHASE Scientific with exclusive U.S. distribution rights for FebriDx® and is valued at up to US\$317/ A\$487 million. Upon execution, US\$2.0 million was payable immediately comprising a US\$1.0 million exclusivity fee (now paid) and a US\$1.0 million pre-paid purchase order payment (expected in the next few days). A further US\$1.5 million pre-paid purchase order will become payable on FebriDx® CLIA waiver application submission to the FDA, expected within three months. An additional US\$5.0 million, non-refundable, prepaid purchase commitment will be payable upon the anticipated granting of CLIA waiver.

Further details are available in the ASX release dated 16 July 2025. A webinar was held on 16 July 2025 where members of the Lumos team discussed the partnership in more detail, together with Bob Gergen, VP of Commercial Operations for PHASE Scientific. A recorded copy of the webinar is available for <u>viewing</u>, <u>here</u>.

**CLIA waiver study update:** Lumos commenced the FebriDx® CLIA waiver study in the U.S., with the first patient successfully tested on 19 December 2024. It is anticipated that between 500 – 800 patients will need to be recruited across at least six sites to achieve the targeted 120 positive bacterial cases for the study.

As at 9 July 2025, the study had enrolled 105 of the targeted 120 bacterial positive patients. The Company is very pleased with progress and at the current accrual rate, the study is anticipated to be completed during August, with an FDA CLIA waiver application expected to be submitted within approximately one month of completion, ahead of the previously guided timeline.

On 18 June the Company announced that it had successfully recruited its 500<sup>th</sup> patient in the study, triggering a milestone payment of US\$298,457 (now received) from clinical study partner, the Biomedical Advanced Research and Development Authority ("BARDA"). BARDA milestone payments received to date total US\$1,223,674. The next BARDA milestone payment of US\$746,143 will be triggered on the achievement of the Last Patient Enrolled in the study. Total committed milestone payments for granting of FDA CLIA waiver for FebriDx® under the BARDA partnership are valued at US\$2,984,571.

**iMedical purchase order:** In May, Lumos received and shipped its largest single FebriDx® purchase order to date, totaling US\$126,000 from iMedical Inc., a leader in developing and delivering innovative cost-saving solutions tailored for hospitals, surgery centers, clinics, and healthcare facilities nationwide across the U.S. The size of the order signals an increase in U.S. customer adoption as well as continued market acceptance of the novel point-of-care test.

**U.S. payor coverage adoption:** On 5 December 2024, Lumos received approval from the Centers for Medicare and Medicaid Services (CMS) Panel for the FebriDx® Proprietary Laboratory Analyses (PLA) code 0442U, to be reimbursed at a rate of US\$41.38 per test. The FebriDx® PLA code was published on the Clinical Lab Fee Schedule and took effect on 1 January 2025.

Securing the reimbursement rate from CMS via PLA Code 0442U was a critical first step. Payment (coverage) of the PLA Code to healthcare providers by the payors (Medicare and private insurance) is not automatic and must be secured. Medicare comprises approximately 20% –24% of the U.S. payor mix and often sets a precedent for private payors. To date, Lumos has successfully secured six of the seven Medicare Administrative Contractors (MACs), responsible for managing Medicare payments in their respective U.S. regions. This represents 85% of U.S. Medicare payor coverage. Positive discussions are continuing with the remaining MAC.

Importantly, the reimbursement pathway already encompasses both Moderately-Complex and CLIA-waived settings. Should Lumos be successful with having FebriDx® granted CLIA waiver, this will in time allow FebriDx® to seamlessly transition across the two testing environments, without repeating the reimbursement process.

Medicare Benefits Schedule Application - Australia: In late March 2025, Lumos completed and lodged an application with the Australian Government Department of Health and Aged Care for the inclusion of FebriDx® on the Medicare Benefits Schedule (MBS). Our initial application for FebriDx® to be listed in the MBS was not successful. Lumos is currently in communication with the Department to discuss possible remedial actions.

#### Women's Sexual Health Product Development

Good progress has been achieved in identifying and developing a pipeline of future women's sexual health point-of-care diagnostic tests. The company is currently exploring five potential products aimed at addressing key unmet needs in this important and growing healthcare segment. These initiatives form part of Lumos' broader commitment to improving access, convenience, and early detection through innovative diagnostic solutions designed specifically for women.

Of the five potential products, three are currently in the concept development stage, with two advancing to technical feasibility. These early milestones are encouraging and reflect the Company's disciplined and evidence-based approach to innovation. Lumos is targeting the transition of at least one of these products into formal product development within the next 6 - 8 months, as the Company continues to build a robust pipeline focused on delivering impactful solutions in women's health.

# Post Release Date: Non-Dilutive Funding Secured

On 17 July, Lumos entered into a binding conditional term sheet for a secured A\$5.0 million loan facility with supportive major shareholders Tenmile and Ryder Capital. Once a definitive agreement is executed, the facility will provide funding, as required, up to a maximum A\$5.0 million over a term of 12 months, with an option to extend the term for a further 12 months.

The loan facility is intended to provide access to working capital through and past the anticipated granting of CLIA waiver for FebriDx® while limiting dilution.

Further details are available in the ASX release dated 17 July 2025.

#### **Summary of Cash Receipts and Outflows**

The net operating cash outflow for Q4 FY25 was US\$1.7 million, an increase of US\$0.4 million from the previous quarter.

Lumos generated cash receipts from customers of US\$1.8 million for the fourth quarter ended 30 June 2025.

Cash operating expenses for Q4 were US\$3.5 million, a decrease of US\$0.2 million over Q3 FY25 expenses of \$3.7 million. This was primarily due to improved working capital movements.

Lumos invoiced BARDA US\$0.3 million during the quarter, which was received in July (post reporting date), representing a milestone payment for recruitment of the 500<sup>th</sup> patient in the FebriDx® CLIA waiver study.

During the quarter Lumos received an Australian Research & Development Tax Incentive rebate of US\$0.14 million (A\$0.22 million) for the year ended 30 June 2024.

As in prior quarters, there was essentially no capital expenditure during Q4 FY25.

After including investing activities and lease payment expenses, net cash outflow for the quarter totaled US\$2.0 million.

Lumos finished Q4 FY25 with a cash balance of US\$2.0 million.

#### **Payments to Related Entities**

In accordance with Listing Rule 4.7C.3 and as outlined in Section 6.1 of Appendix 4C, the Company discloses payments to related entities of US\$223,000, comprising directors' fees, consulting fees, salary & wages and superannuation.

# **Key Priorities**

The key focus areas for Lumos are currently summarized as follows:

- Complete CLIA waiver study and submit application to FDA
- Implement agreement with PHASE Scientific, drive reimbursement coverage, and plan for volume scaleup
- Initiate the BARDA pediatric study in coming months to address an important clinical market and expand the U.S. market for FebriDx® by approx. 20%
- Deliver on Hologic fFN development milestones milestone 3 assay feasibility additional SOW from Phase 2 & the Phase 3 milestones
- Progress to formal product development for the first Lumos branded women's health diagnostics test

In closing, CEO Doug Ward said: "The past few months have been critical for Lumos and for FebriDx®, marked by a series of very significant milestones that are not only advancing our U.S. regulatory pathway but also laying the foundation for FebriDx® as a true platform diagnostic. The distribution partnership with PHASE Scientific represents the culmination of years of hard work by our exceptional team. I remain deeply confident in the tangible benefits of FebriDx® and the meaningful impact it can have on patient care, clinical decision-making, and broader healthcare system efficiencies."

"Our CLIA Waiver study for FebriDx® continues to progress well, with study completion expected around August 2025, with our FDA CLIA waiver application expected to be submitted within approximately one month of completion. Encouragingly, we've seen strong early support from U.S. public payors, which we believe will be the catalyst for broader adoption by private payors in due course."

"I'm sincerely grateful for the continued backing of our two largest shareholders, Tenmile and Ryder Capital. The non-dilutive funding facility, along with contracted FebriDx® distribution fees and future milestone payments from our partners, positions Lumos well to meet working capital needs as we advance towards the anticipated granting of CLIA waiver."

"Looking ahead, we remain firmly focused on our strategic priorities and committed to building a strong, sustainable business that delivers long-term value for patients, partners, and shareholders alike."

#### **Investor Briefing**

The Company invites investors and analysts to attend an online briefing on Friday, 25 July 2025 at 11:00am (AEST).

During the briefing, Chief Executive Officer, Doug Ward and Chief Financial Officer, Barrie Lambert will present an overview of the results and discuss recent progress. This will be followed by a Q+A session.

Participants can pre-register ahead of time via the following link:

https://us02web.zoom.us/webinar/register/WN vEpdFyAYQgaRLQviaoPBtA

Once the registration form is completed, investors will receive a confirmation email with details on how to access the briefing. The Lumos team looks forward to welcoming those shareholders and potential investors who are able to attend.

-Ends-

This announcement has been approved by the Lumos Disclosure Committee.

# **About Lumos Diagnostics**

Lumos Diagnostics specializes in rapid and complete point-of-care diagnostic test technology to help healthcare professionals more accurately diagnose and manage medical conditions. Lumos offers customized assay development and manufacturing services for point-of-care tests and proprietary digital reader platforms. Lumos also directly develops, manufactures, and commercializes novel Lumos-branded point-of-care tests that target infectious and inflammatory diseases.

For more information visit lumosdiagnostics.com.

#### **Forward-Looking Statements**

This announcement contains forward-looking statements, including references to forecasts. Forward-looking statements are not guarantees of future performance and involve known and unknown risks, uncertainties, assumptions, and other important factors, many of which are beyond Lumos' control and speak only as of the date of this announcement. Readers are cautioned not to place undue reliance on forward-looking statements.

#### **Media Contacts:**

Haley Chartres – Australia H^CK Director haley@hck.digital +61 423 139 163

# **Investor Contact:**

George Kopsiaftis
IR Specialist, IR Department
ir@lumosdiagnostics.com
+61 409 392 687

# **Company Registered Office:**

Lumos Diagnostics Holdings Ltd Suite 2, Level 11 385 Bourke Street Melbourne VIC 3000 Australia info@lumosdiagnostics.com +61 3 9087 1598

# **Appendix 4C**

# Quarterly Cash Flow report for entities subject to Listing Rule 4.7B

# Name of entity

66 630 476 970

Lumos Diagnostics Holding Limited

ABN

Quarter ended ("current quarter")

30 June 2025

Consolidated statement of cash flows		Current quarter US\$'000	Year to date (12 months) US\$'000	
1.	Cash flows from operating activities			
1.1	Receipts from customers	1,820	6,368	
1.2	Payments for			
	(a) service delivery, research and development	(820)	(3,425)	
	(b) product manufacturing and operating costs	(566)	(3,242)	
	(c) sales, advertising and marketing	(347)	(1,417)	
	(d) medical affairs and clinical trial costs	(292)	(1,037)	
	(e) leased assets	-	-	
	(f) staff costs*	(956)	(4,957)	
	(g) administration and corporate costs	(551)	(2,266)	
1.3	Dividends received (see note 3)	-	-	
1.4	Interest received	6	56	
1.5	Interest and other costs of finance paid	(137)	(581)	
1.6	Income taxes paid	-	-	
1.7	Government grants and tax incentives	139	1,157	
1.8	Other (provide details if material)	-	-	
1.9	Net cash from / (used in) operating activities	(1,704)	(9,344)	

<sup>\*</sup>Staff costs have been allocated to their respective departments above.

2.	Cash flows from investing activities		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(18)	(43)
	(d) investments	-	-

Cons	solidated statement of cash flows	Current quarter US\$'000	Year to date (12 months) US\$'000
	(e) intellectual property	-	-
	<ul> <li>(f) other non-current assets (including capitalised product development costs)</li> </ul>	-	-
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	(18)	(43)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	6,765
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	-	(543)
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 (principal component)	(257)	(946)
3.10	Net cash from / (used in) financing activities	(257)	5,276

Con	solidated statement of cash flows	Current quarter US\$'000	Year to date (12 months) US\$'000
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	3,974	6,479
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,704)	(9,344)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(18)	(43)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(257)	5,276
4.5	Effect of movement in exchange rates on cash held	(39)	(412)
4.6	Cash and cash equivalents at end of period	1,956	1,956

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 US\$'000	Previous quarter US\$'000
5.1	Bank balances	1,956	3,974
5.2	Call deposits	-	-
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)	1,956	3,974

6.	Payments to related parties of the entity and their associates	Current quarter US\$'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	223
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
	if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must includnation for, such payments.	le a description of, and an

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 US\$'000	Amount drawn at quarter end US\$'000
7.1	Loan facilities	3,263	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	Total financing facilities	3,263	-
7.5	Unused financing facilities available at qu	arter end	3,263

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.

Item 7.1 includes a loan facility of A\$5.0 million announced on 17 July 2025.

The company entered into a binding, conditional secured loan facility of A\$5.0 million with major shareholders Tenmile Ventures Pty Ltd and Ryder Capital Management Pty Ltd.

The interest rate on drawn amounts is 15.0% per annum.

Maturity date is 12 months from the first drawdown date, with options to extend for a further 12 months.

Drawdowns are at the discretion of the Company.

The amount shown above is for the full loan facility of A\$5.0 million at an FX rate of A\$1.00:US\$0.6526.

Refer to the ASX announcement for further details on this loan facility.

8.	Estimated cash available for future operating activities	US\$'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,704)
8.2	Cash and cash equivalents at quarter end (item 4.6)	1,956
8.3	Unused finance facilities available at quarter end (item 7.5)	3,263
8.4	Total available funding (item 8.2 + item 8.3)	5,219
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	3.1x
	Note: if the entity has reported positive net operating cash flows in item 1.9, answer item	n 8 5 as "N/A" Otherwise a

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	Ar	swer:	Ν	/A
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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: 21 July 2025

Authorised by: The Lumos Disclosure Committee

(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.