

APPENDIX 4C QUARTERLY ACTIVITY REPORT***Mesoblast Operational and Financial Highlights for Quarter Ended March 31, 2021***

Melbourne, Australia; April 30 and New York, USA; April 29, 2021: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today provided an update on its pipeline of late-stage product candidates, and an activity report for the third quarter ended March 31, 2021.

“We are very excited about the top-line results announced today from the trial of remestemcel-L in patients on mechanical ventilation due to COVID-19. These showed that remestemcel-L reduced mortality through 60 days in the pre-specified population under 65 years old, particularly when used with dexamethasone as part of standard of care. This has the potential to make a substantial impact in outcomes for this critical patient population,” said Silviu Itescu, Chief Executive of Mesoblast.

Corporate and operational highlights included:

- Successful completion of US\$110 million private placement, with cash balance March 31, 2021, of US\$158.3 million
- Private placement was led by US investor group SurgCenter Development (SurgCenter), one of the largest private operators of ambulatory surgical centers (ASC) in the US specializing in spine, orthopaedic and total joint procedures.
- Appointment of Philip J. Facchina, Chief Strategy Officer of SurgCenter, to the Mesoblast Board of Directors
- Results from the randomized controlled trial of remestemcel-L in 222 ventilator-dependent COVID-19 patients with moderate/severe acute respiratory distress syndrome (ARDS) showed that patients who received remestemcel-L had a reduced mortality through 60 days in the pre-specified population under 65 years old
- In these patients the benefit was further increased when remestemcel-L was used with dexamethasone as part of standard of care
- The trial also showed that the mortality reduction by remestemcel-L was accompanied by increased days alive off mechanical ventilation and reduced days in hospital
- Results from the trial of rexlemestrocel-L (MPC-06-ID) in 404 patients with chronic low back pain (CLBP) due to degenerative disc disease (DDD) showed that a single injection of rexlemestrocel-L + hyaluronic acid (HA) carrier may provide at least two years of pain reduction, with opioid sparing activity in patients using opioids at baseline
- Significant and durable reductions in CLBP through 24 months were seen across the entire evaluable study population, and greatest pain reduction was observed in the pre-specified population with CLBP of shorter duration than the study median of 68 months
- The results indicate that treatment benefit may be greatest when inflammation is high and before irreversible fibrosis has occurred in the intervertebral disc

Remestemcel-L

Acute Respiratory Distress Syndrome due to COVID-19

Mesoblast Limited today announced the 60 day results from the randomized controlled trial of remestemcel-L in 222 ventilator-dependent COVID-19 patients with moderate/severe acute respiratory distress syndrome (ARDS) which had been halted after the third interim analysis, as previously announced. Remestemcel-L reduced mortality through day 60 by 46% in the pre-specified group below age 65, but not in patients 65 or older. Remestemcel-L reduced mortality by 75% and increased days alive off mechanical ventilation in patients under age 65 when combined with dexamethasone, in comparison with controls on dexamethasone.

Reduction in mortality in mechanically ventilated patients under 65 years old remains a critical unmet need since as many as 72% of currently hospitalized patients across the US with COVID-19 are in this age category.¹ This is similar to other causes of viral ARDS such as influenza where 70-80% of patients in intensive care units are under 65.^{2,3} The trial enrolled 222 mechanically ventilated COVID-19 patients with moderate/severe ARDS across the US, of whom 217 were randomized 1:1 and received either standard of care alone or standard of care plus 2 intravenous infusions of remestemcel-L at a dose of 2 million cells/kg 3-5 days apart. This was the same remestemcel-L dosing regimen used in the earlier compassionate use program where 11 of the 12 patients were younger than 65 and 75% successfully came off ventilatory support.

Key findings in the trial were:

- Remestemcel-L reduced mortality by 46% through day 60 in the pre-specified population of 123 treated patients under age 65, 26% vs 42%, Hazard Ratio (HR) 0.54, 95% CI (0.286, 1.005), $p=0.048^{4,5}$
- Remestemcel-L had similar treatment effects on mortality in these patients with either moderate ARDS (HR 0.56)^{5,6} or severe ARDS (HR 0.56)^{5,6}
- Standard of care changed during the course of the trial to incorporate dexamethasone, with only 2% of the first 50 patients enrolled receiving dexamethasone compared with 84% of the subsequent 172 patients; this allowed for additional exploratory analyses of remestemcel-L treatment effects in patients who received dexamethasone as part of their standard of care
- Remestemcel-L reduced mortality through day 60 by 75% compared to controls in patients under 65 who received dexamethasone as part of their standard of care, 14% vs 45%, HR 0.25, 95% CI (0.085, 0.727), $p=0.006^{4,5}$
- Remestemcel-L increased days alive off ventilator within 60 days and reduced time to discharge from initial hospitalization compared to controls in patients under 65 who received dexamethasone as part of their standard of care, $p=0.01$ and $p=0.005$, respectively^{4,7}

Mesoblast entered into a license and collaboration agreement with Novartis for the development, manufacture, and commercialization of remestemcel-L, with an initial focus on the treatment of acute respiratory distress syndrome (ARDS), including that associated with COVID-19. The agreement remains subject to certain closing conditions, including time to analyze the results from this COVID-19 ARDS trial.

Steroid-Refractory Acute Graft Versus Host Disease

On August 13, 2020, results from 309 children with steroid-refractory acute graft versus host disease (SR-aGVHD) treated with remestemcel-L were presented to the Oncologic Drugs Advisory Committee (ODAC) of the United States Food and Drug Administration. The ODAC panel voted 9:1 that the available data support the efficacy of remestemcel-L in pediatric patients with SR-aGVHD⁸. Despite the overwhelming ODAC vote, on September 30, the FDA provided Mesoblast with a Complete Response Letter.

Mesoblast held a Type A meeting with the FDA in November 2020 to discuss the review of the Biologics License Application for remestemcel-L. The current review team have not agreed to accelerated or full approval. However, there was consensus with the review team on the proposed

optimization of potency assays and on use of biomarkers to demonstrate the product's bioactivity in-vivo.

Mesoblast continues to be in discussion with the FDA through a well-established process with the goal of achieving approval for remestemcel-L to treat SR-aGVHD.

Inflammatory Bowel Disease – Crohn's Disease and Ulcerative Colitis

A randomized, controlled study of remestemcel-L delivered by an endoscope directly to the areas of inflammation and tissue injury in up to 48 patients with medically refractory Crohn's disease and ulcerative colitis commenced at Cleveland Clinic in October 2020. The investigator-initiated study is the first in humans using local cell delivery in the gut and will enable Mesoblast to compare clinical outcomes using this delivery method with results from an ongoing randomized, placebo-controlled trial in patients with biologic-refractory Crohn's disease where remestemcel-L was administered intravenously.

Rexlemestrocel-L

Revascor for Chronic Heart Failure

The results from the landmark DREAM-HF randomized controlled trial in 537 treated patients with chronic heart failure with reduced left ventricular ejection fraction (HFrEF) who received rexlemestrocel-L (REVASCOR®) or control sham, demonstrated that a single dose of rexlemestrocel-L resulted in substantial and durable reductions in heart attacks, strokes, and cardiac deaths. The results of this trial identify New York Heart Association (NYHA) class II HFrEF patients as the optimal target population for greatest rexlemestrocel-L treatment effect, and therefore a focus for registration and commercialization of rexlemestrocel-L in the largest market in heart failure.

Based on the observed reduction in mortality and morbidity in this trial, Mesoblast intends to meet with the FDA to discuss a potential approval pathway. Concurrently, Mesoblast will also explore potential strategic initiatives with a number of global pharma companies who have existing interests in cardiovascular disease and/or major vascular complications of diabetes.

MPC-06-ID for Chronic Low Back Pain due to Degenerative Disc Disease

The results from the randomized controlled trial of its allogeneic mesenchymal precursor cell (MPC) therapy rexlemestrocel-L in 404 enrolled patients with chronic low back pain (CLBP) due to degenerative disc disease (DDD) refractory to conventional treatments indicate that a single injection of rexlemestrocel-L + hyaluronic acid (HA) carrier may provide a safe, durable, and effective opioid-sparing therapy for patients with chronic inflammatory back pain due to degenerative disc disease, and that greatest benefits are seen when administered earlier in the disease process before irreversible fibrosis of the intervertebral disc has occurred.

There is a significant need for a safe, efficacious, and durable opioid-sparing treatment in patients with chronic low back pain due to severely inflamed degenerative disc disease. Mesoblast intends to meet with FDA to discuss a potential pathway for approval of rexlemestrocel-L in patients with chronic discogenic lower back pain based on the observed durable reduction in pain and opioid sparing activity in the CLBP trial.

Cash Flow Report for the Third Quarter FY2021

Successfully completed a US\$110 million (A\$138 million) private placement led by a US strategic investor group in March 2021. Cash on hand at the end of the quarter was US\$158.3 million (A\$208.2 million).

Total Operating Activities resulted in net cash usage of US\$25.8 million in the quarter ended March 31, 2021. This included an investment of US\$11.5 million associated with remestemcel-L for SR-aGVHD and COVID-19 ARDS. Specifically:

- Sales of TEMCELL® HS Inj.⁹ in Japan for the treatment of aGVHD continue to recover from the effects of the temporary shutdown in production during mid-2020 which was undertaken in order to increase capacity to meet growing demand for the product
- Revenues from TEMCELL® royalties for the quarter ended March 31, 2021 were US\$1.9 million compared to US\$2.0 million in the quarter ended March 31, 2020. Royalty receipts for the quarter were US\$2.2 million, reflecting revenues recognized in the prior quarter
- Research and Development payments were US\$11.7 million for the current quarter. This comprises payments for the recently completed trials in COVID-19 ARDS, CHF and CLBP, as well as potency assay work in support of these programs.
- Product manufacturing & operating costs and manufacturing commercialization payments were US\$5.9 million for the current quarter, the majority being for commercial manufacturing and inventory build in anticipation for product launch of remestemcel-L
- Payments to Related Parties, detailed in Item 6 of the Appendix 4C cash flow report for the quarter, comprise approximately US\$418,000 in Non-Executive Director fees and Executive Director's salary

A copy of the Appendix 4C – Quarterly Cash Flow Report for the third quarter FY2021 is attached.

Conference Call

There will be a webcast today, beginning at 9.00am AEST (Friday, April 30); 7.00pm EDT (Thursday, April 29, 2021). It can be accessed via:

<https://webcast.boardroom.media/mesoblast-limited/20210427/NaN60874bd69634a7001901f0a6>

The archived webcast will be available on the Investor page of the Company's website:

www.mesoblast.com

About Mesoblast

Mesoblast is a world leader in developing allogeneic (off-the-shelf) cellular medicines for the treatment of severe and life-threatening inflammatory conditions. The Company has leveraged its proprietary mesenchymal lineage cell therapy technology platform to establish a broad portfolio of late-stage product candidates which respond to severe inflammation by releasing anti-inflammatory factors that counter and modulate multiple effector arms of the immune system, resulting in significant reduction of the damaging inflammatory process.

Mesoblast has a strong and extensive global intellectual property portfolio with protection extending through to at least 2040 in all major markets. The Company's proprietary manufacturing processes yield industrial-scale, cryopreserved, off-the-shelf, cellular medicines. These cell therapies, with defined pharmaceutical release criteria, are planned to be readily available to patients worldwide.

Mesoblast has completed Phase 3 trials of rexlémestrocél-L for advanced chronic heart failure and chronic low back pain. Remestemcel-L is being developed for inflammatory diseases in children and adults including steroid refractory acute graft versus host disease and moderate to severe acute respiratory distress syndrome. Two products have been commercialized in Japan and Europe by Mesoblast's licensees, and the Company has established commercial partnerships in Europe and China for certain Phase 3 assets.

Mesoblast has locations in Australia, the United States and Singapore and is listed on the Australian Securities Exchange (MSB) and on the Nasdaq (MESO). For more information, please see www.mesoblast.com, LinkedIn: Mesoblast Limited and Twitter: @Mesoblast

References / Footnotes

Footnotes

1. The Coronavirus Disease 2019 (COVID-19)-Associated Hospitalization Surveillance Network (COVID-NET). Centers for Disease Control and Prevention

2. Martin-Loeches et al. Pandemic and post-pandemic Influenza A (H1N1) infection in critically ill patients *Critical Care* 2011, 15:R286
3. Bonmarin I et al. Intensive care unit surveillance of influenza infection in France: the 2009/10 pandemic and the three subsequent seasons. *Euro Surveill.* 2015;20(46)
4. All p-values are descriptive and not adjusted for multiplicity
5. Hazard Ratios calculated using Cox regression proportional hazards model without adjustment; p-value from Kaplan-Meier log rank statistics
6. Interaction term between remestemcel-L treatment and ARDS severity in Cox regression proportional hazards model was not significant (p=0.98), indicating that treatment effect is not confounded by disease severity
7. Wilcoxon rank sum test
8. This vote includes a change to the original vote by one of the ODAC panel members after electronic voting closed
9. TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.

Forward-Looking Statements

This announcement includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Forward-looking statements should not be read as a guarantee of future performance or results, and actual results may differ from the results anticipated in these forward-looking statements, and the differences may be material and adverse. Forward-looking statements include, but are not limited to, statements about the initiation, timing, progress and results of Mesoblast's preclinical and clinical studies, and Mesoblast's research and development programs; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials; Mesoblast's ability to advance its manufacturing capabilities; the timing or likelihood of regulatory filings and approvals, manufacturing activities and product marketing activities, if any; the commercialization of Mesoblast's product candidates, if approved; regulatory or public perceptions and market acceptance surrounding the use of stem-cell based therapies; the potential for Mesoblast's product candidates, if any are approved, to be withdrawn from the market due to patient adverse events or deaths; the potential benefits of strategic collaboration agreements and Mesoblast's ability to enter into and maintain established strategic collaborations; Mesoblast's ability to establish and maintain intellectual property on its product candidates and Mesoblast's ability to successfully defend these in cases of alleged infringement; the scope of protection Mesoblast is able to establish and maintain for intellectual property rights covering its product candidates and technology; estimates of Mesoblast's expenses, future revenues, capital requirements and its needs for additional financing; Mesoblast's financial performance; developments relating to Mesoblast's competitors and industry; and the pricing and reimbursement of Mesoblast's product candidates, if approved. You should read this press release together with our risk factors, in our most recently filed reports with the SEC or on our website. Uncertainties and risks that may cause Mesoblast's actual results, performance or achievements to be materially different from those which may be expressed or implied by such statements, and accordingly, you should not place undue reliance on these forward-looking statements. We do not undertake any obligations to publicly update or revise any forward-looking statements, whether as a result of new information, future developments or otherwise.

Release authorized by the Chief Executive.

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Appendix 4C

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

Name of entity

Mesoblast Limited

ABN

68 109 431 870

Quarter ended ("current quarter")

31 March 2021

Consolidated statement of cash flows	Current quarter \$US'000	Year to date (9 months) \$US'000
1. Cash flows from operating activities		
1.1 Receipts from customers		
- royalty receipts	2,190	4,162
1.2 Payments for		
(a) research and development	(11,748)	(35,184)
(b) manufacturing commercialization	(2,852)	(10,978)
(c) product manufacturing and operating costs	(2,999)	(13,139)
(d) advertising and marketing	(1,937)	(5,823)
(e) leased assets	—	—
(f) staff costs	(1,995)	(8,080)
(g) other expenses from ordinary activities	(4,402)	(10,518)
(h) other:		
- Intellectual property portfolio expenses	(739)	(2,307)
1.3 Dividends received (see note 3)	—	—
1.4 Interest received	1	17
1.5 Interest and other costs of finance paid	(1,351)	(4,122)
1.6 Income taxes paid	(29)	(35)
1.7 Government grants and tax incentives	39	56
1.8 Other (provide details if material)	—	—
1.9 Net cash from / (used in) operating activities	(25,822)	(85,951)

Consolidated statement of cash flows	Current quarter \$US'000	Year to date (9 months) \$US'000
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(i) entities	—	—
(j) businesses	—	—
(k) property, plant and equipment	(936)	(1,424)
(l) investments	—	—
(m) intellectual property	—	—
(n) other non-current assets	—	—
2.2 Proceeds from disposal of:		
(o) entities	—	—
(p) businesses	—	—
(q) property, plant and equipment	—	—
(r) investments	—	—
(s) intellectual property	—	—
(t) other non-current assets	—	—
2.3 Cash flows from loans to other entities	—	—
2.4 Dividends received (see note 3)	—	—
2.5 Other	—	—
2.6 Net cash from / (used in) investing activities	(936)	(1,424)

3. Cash flows from financing activities		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	108,585	110,014
3.2 Proceeds from issue of convertible debt securities	—	—
3.3 Proceeds from exercise of options	403	8,539
3.4 Transaction costs related to issues of equity securities or convertible debt securities	(642)	(1,547)
3.5 Proceeds from borrowings	—	—
3.6 Repayment of borrowings	—	—
3.7 Transaction costs related to loans and borrowings	(13)	(13)
3.8 Dividends paid	—	—

Consolidated statement of cash flows		Current quarter \$US'000	Year to date (9 months) \$US'000
3.9	Other (payment of lease liability)	(620)	(2,100)
3.10	Net cash from / (used in) financing activities	107,713	114,893

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of quarter (October 1, 2020)/beginning of year (July 1, 2020)	77,528	129,328
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(25,822)	(85,951)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(936)	(1,424)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	107,713	114,893
4.5	Effect of movement in exchange rates on cash held	(220)	1,417
4.6	Cash and cash equivalents at end of period	158,263	158,263

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	157,807	77,065
5.2	Call deposits	—	—
5.3	Bank overdrafts	—	—
5.4	Other (Term deposits)	456	463
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	158,263	77,528

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	418
6.2 Aggregate amount of payments to related parties and their associates included in item 2	—

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 for Non-executive Director fees and Executive Director's salary (for the current quarter) = US\$418,000

7. Financing facilities <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	Total facility amount at quarter end \$US'000	Amount drawn at quarter end \$US'000
7.1 Loan facilities	90,000*	80,000*
7.2 Credit standby arrangements	—	—
7.3 Other (please specify)	—	—
7.4 Total financing facilities	90,000*	80,000*
7.5 Unused financing facilities available at quarter end		10,000*
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.		
<p><u>*Loan facility with Hercules Capital, Inc.</u></p> <p>On March 6, 2018, Mesoblast entered into a Loan and Security Agreement with Hercules Capital, Inc. ("Hercules Capital") for a US\$75.0 million secured four-year credit facility. Mesoblast drew the first tranche of US\$35.0 million on closing. An additional US\$15.0 million was drawn during Q1 CY2019.</p> <p>As at March 31, 2021, the interest rate on the loan was 9.70%.</p> <p><u>*Loan facility with NovaQuest Capital Management, L.L.C.</u></p> <p>On June 29, 2018, Mesoblast entered into a Loan and Security Agreement with NovaQuest Capital Management, L.L.C. ("NovaQuest") for a non-dilutive US\$40.0 million secured eight-year term loan. Mesoblast drew the first tranche of US\$30.0 million of the loan on closing. An additional US\$10.0 million from the loan will be drawn on marketing approval of RYONCIL by the United States Food and Drug Administration (FDA).</p> <p>Prior to maturity in July 2026, the loan is only repayable from net sales of RYONCIL in the treatment of pediatric patients who have failed to respond to steroid treatment for acute Graft versus Host Disease (aGvHD), in the United States and other geographies excluding Asia. Interest on the loan will accrue at a rate of 15% per annum with the interest only period lasting 4 years. Interest payments will be deferred until after the first commercial sale. The financing is subordinated to the senior creditor, Hercules Capital.</p>		

8. Estimated cash available for future operating activities	\$US'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(25,822)
8.2 Cash and cash equivalents at quarter end (item 4.6)	158,263
8.3 Unused finance facilities available at quarter end (item 7.5)	10,000*
8.4 Total available funding (item 8.2 + item 8.3)	168,263
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	6.5
<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>	
* Under the NovaQuest loan facility, an additional US\$10.0 million from the loan will be drawn on marketing approval of RYONCIL by the United States Food and Drug Administration (FDA).	
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: Not applicable	
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: Not applicable	
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: Not applicable	
<i>Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.</i>	

Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date:30 April 2021.....

Authorised by:Chief Executive.....
(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.