

ASX: ALA

Arovella Therapeutics Limited
ACN 090 987 250



ASX Release

23 January 2026

APPENDIX 4C: SECOND QUARTER FY26

Highlights for the quarter:

- Cash and cash equivalents at 31 December of \$19.4 million
- Filed Investigational New Drug (IND) application for ALA-101 to U.S. FDA
- In readiness for the first-in-human phase 1 trial for ALA-101, CRO was selected
- Demonstrated potent activity of new CLDN18.2-targeting CAR for ALA-105 program
- Exercised an Option for in-licencing of additional CAR-targets and iNKT-related technology from Baylor College of Medicine
- Appointed Dr Andrew Nash to Arovella Board of Directors

MELBOURNE, AUSTRALIA 23 January 2026: Arovella Therapeutics Limited (ASX: ALA) (**Arovella** or the **Company**), a biotechnology company focused on developing its invariant Natural Killer T (iNKT) cell therapy platform, today releases its Appendix 4C for the second quarter of FY26.

During the quarter, Arovella achieved an important milestone for its lead program, filing an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) to support a first-in-human clinical trial for ALA-101. The Company also initiated clinical trial start-up activities, including selection of a contract research organisation (CRO), SAPRO, to provide support for the phase 1 trial of ALA-101 for patients with CD19-positive lymphoma and leukaemia. The Company continued to expand its platform into solid tumours with data supporting the activity of its novel claudin 18.2-targeting chimeric antigen receptor (CAR) and the exercise of an Option from Baylor College of Medicine for in-licencing additional CAR targets and technology relating to the manufacture of CAR-iNKT cells.

The Company finished the fourth quarter with cash of \$19.4 million, which is expected to fund the Company through to the completion of patient enrolment for the phase 1 clinical trial for ALA-101. The funding will also support the advancement of the Company's solid tumour programs (CLDN18.2 CAR-iNKT cells targeting gastric cancer) and its armouring program (IL-12-TM).

Arovella's CEO and MD, Dr Michael Baker, remarked, "Following the positive feedback from the FDA during the type D meeting, it was excellent to submit the IND to the FDA. This is a significant milestone for the company, and we look forward to their feedback, which we expect in the short term. The Company is in an excellent position financially, with a strong balance sheet that will support the phase 1 study and the expansion of our products being developed for solid tumours. It was also a pleasure to welcome Dr Andrew Nash to our Board of Directors. As someone with a strong background in early-stage therapeutic development, through to capital raising, M&A and the commercialisation of therapeutics, the Company will benefit greatly from his experience. 2026 is setting up to be a transformative year for Arovella and we look forward to transitioning to a clinical stage Company."

TAKING ALA-101 INTO A FIRST-IN-HUMAN PHASE 1 CLINICAL TRIAL

In December, Arovella submitted an Investigational New Drug (IND) application to the U.S. FDA for its lead cell therapy candidate, ALA-101, an allogeneic CAR-iNKT cell therapy targeting CD19-positive non-Hodgkin's lymphoma (NHL) and leukaemias.

The IND submission represents a major operational and regulatory milestone for Arovella, enabling the Company to progress ALA-101 towards its first-in-human Phase 1 clinical trial, pending FDA clearance. FDA review of the IND application typically occurs within 30 days.

ALA-101 is Arovella's lead allogeneic cell therapy product derived from iNKT cells engineered to express a CD19-specific chimeric antigen receptor (CAR). An allogeneic product offers several potential advantages over first-generation CAR-T approaches, including a manufacturing process that is scalable and cost-efficient, enabling "off-the-shelf" dosing to reduce the time to treatment for patients and improving access. Obtaining an active IND is a critical step for Arovella as it enables the Company to conduct its phase 1 trial in Australia via the Clinical Trial Notification (CTN) scheme rather than the lengthier Clinical Trial Application (CTA) pathway. It also enables Arovella to open clinical trial sites in the U.S.

In parallel with the IND preparation, Arovella has also initiated start-up activities for its phase 1 study for ALA-101. The phase 1 study is an open-label, dose escalation and dose expansion trial targeting CD19-positive non-Hodgkin's lymphoma and leukemia with initial clinical sites anticipated to be located across Australia and New Zealand. The initial dose escalation part of the trial will assess the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary efficacy of a single dose of ALA-101 and establish the maximum tolerated dose (MTD) for the expansion phase. A Bayesian design will be employed to enable efficient dose escalation and to maximise the likelihood that patients are enrolled at a safe and effective dose. The dose expansion part of the trial will further characterise the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy of ALA-101. The commencement of the trial is subject to human research ethics committee (HREC) approval and local institutional approvals.

In October, Arovella announced the appointment of SAPRO as its clinical research organisation (CRO) for the trial. SAPRO was selected after an extensive and rigorous selection process conducted by the Arovella management team. Arovella anticipates the dose escalation part of the trial to commence in early CY26, pending positive feedback from the FDA for the IND filing, and HREC approval in Australia.

ALA-105, A SOLID TUMOUR PRODUCT TARGETING CLAUDIN 18.2

In October, Arovella announced that it had confirmed the functionality of its novel claudin 18.2 (CLDN18.2)-targeting chimeric antigen receptor (CAR) by demonstrating that CLDN18.2 CAR-T cells robustly eliminate pancreatic cancer cells that express CLDN18.2 *in vitro*. The study confirmed the potent activity of Arovella's CLDN18.2 CAR against a pancreatic cancer cell line, with pancreatic cancer being one of the more aggressive, and low survival cancer types with limited treatment options.

The human pancreatic adenocarcinoma cell line, PaTu8988S, naturally expresses CLDN18.2 and was selected as a model cell line for this study. Arovella's novel CAR design is based on the patent protected CLDN18.2 antigen-binding sequences of the SPX-101 monoclonal antibody, for which Arovella has an exclusive license for use in cell

therapies. CLDN18.2 CAR-T cells generated from three independent donors were cultured *in vitro* with twice the number of PaTu8988S cells for 3 days, and then the degree of cytotoxicity was measured. The results demonstrated that CAR-T cells expressing Arovella's CLDN18.2 CAR displayed robust killing of pancreatic cancer cells (Figure 1), and the activity was similar to that observed for a control CAR generated based upon the CARsgen Therapeutics CT041 CAR, which is currently the most advanced CLDN18.2-targeting CAR-T product.

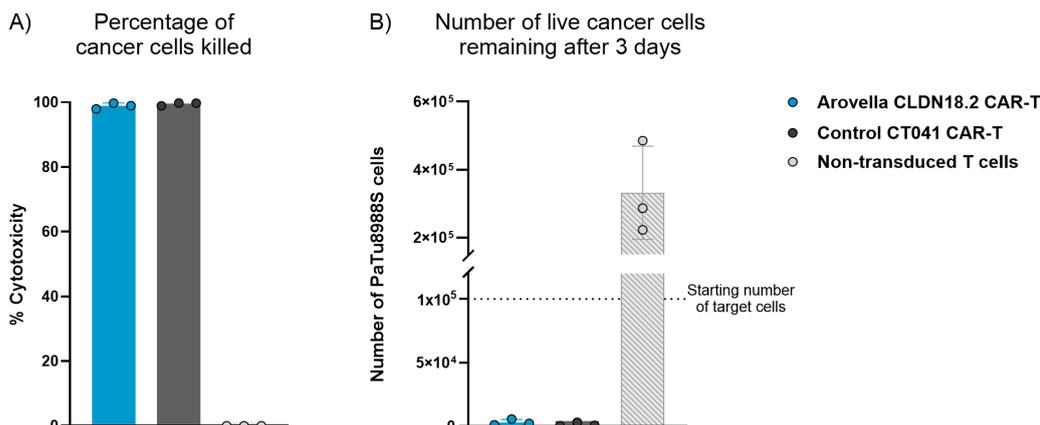


Figure 1. Cytotoxicity of CAR-T cells expressing Arovella's CLDN18.2-targeting CAR against the human pancreatic adenocarcinoma cell line, PaTu8988S. CAR-T cells were cultured with PaTu8988S cells at an effector-to-target ratio of 1:2 for 3 days and then analysed by flow cytometry. (A) Percentage cytotoxicity calculated relative to PaTu8988S target cells cultured with non-transduced T cells, (B) Number of live PaTu8988S target cells remaining following the co-culture with CAR-T cells or non-transduced T cells. Data is presented for three donors \pm Standard Error of the Mean (SEM).

Importantly, recent publications have demonstrated that CAR-iNKT cells outperform CAR-T cells in fighting solid tumours by shaping the tumour microenvironment (TME) and promoting the cross-priming of other cytotoxic immune cells to eliminate the cancer cells^{1,2}. It is anticipated that Arovella's CLDN18.2-CAR-iNKT cells will perform better than CAR-T cells due to their additional functionality within the TME. The next steps for the program are to engineer iNKT cells to express the CLDN18.2 CAR, test the activity of these cells against CLDN18.2 positive cell lines, and commence *in vivo* pancreatic and gastric cancer studies in mice.

EXERCISE OF OPTION FROM BAYLOR COLLEGE OF MEDICINE TO EXPAND PIPELINE

In November 2025, Arovella exercised the Exclusive Option with Baylor College of Medicine (Baylor) to begin negotiations for the chimeric antigen receptor (CAR) and the invariant Natural Killer T (iNKT) cell platform intellectual property. The two Parties continue to work towards a definitive license agreement (DLA) for the technology.

On 5 May 2025, Arovella announced that it entered into an Exclusive Option agreement with Baylor for two new CARs and additional iNKT-related intellectual property with a six-month Option Period. The licence is intended to include access to two new CARs targeting neuroblastoma (GD2) and liver cancer (GPC3), and potentially additional intellectual property relating to CAR-iNKT cells. Both CARs have been used within FDA IND-enabled clinical trials, supporting their safety profiles.

¹ https://www.science.org/doi/10.1126/sciimmunol.abn6563?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

² <https://www.nature.com/articles/s43018-024-00830-0>

DR ANDREW NASH APPOINTED AS NON-EXECUTIVE DIRECTOR

On 12 November 2025, Dr Andrew Nash was appointed as a Non-Executive Director of Arovella. Dr Nash has over 35 years of practical drug development experience and executive leadership in the biotech and pharmaceutical sector, most recently with Australia's largest and most successful pharmaceutical company, CSL. Dr Nash initially trained as an academic scientist after completing his PhD in Immunology. He then joined Zenyth (formerly Amrad Corp), where he advanced to become Chief Scientific Officer (CSO), and ultimately CEO before it was sold to CSL in 2006. Dr Nash was appointed CSO of CSL in 2020 and remained in that position until his retirement in March 2025.

Dr Nash has had a distinguished career, being elected as a Fellow of the Academy of Technological Sciences and Engineering in 2021, and as a Fellow of the Australian Academy of Science in 2025. He was the inaugural Chair of Jumar Bioincubator and is currently a Board Director at the Burnet Institute, the Garvan Institute of Medical Research, Brandon BioCatalyst and Denteric, a vaccine-focused biotechnology company in Melbourne.

The intention is for Dr Nash to transition from the role of Non-Executive Director to Non-Executive Chairman of the Board, and the Company looks forward to providing an update in due course.

FINANCIAL UPDATE

Arovella maintains a strong financial position, with \$19.4 million in cash and cash equivalents as at 31 December 2025.

Cash outflows from operating activities during the quarter was \$2.5 million and the research and development and staff costs for the quarter represented 90% of the Company's operating outflows.

Payments to Related Entities

In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in item 6.1 of Appendix 4C incorporates directors' fees, salaries and superannuation. Payments made for the quarter total \$154,063 and relate to payments to the CEO/Managing Director in accordance with employment contracts and payments to the Non-Executive Directors.

OUTLOOK FOR FY26

Arovella remains in a strong financial position with a solid balance sheet as it advances its lead program, ALA-101, towards a first-in-human phase 1 clinical trial. The trial is expected to commence early in 2026, and the Company is funded to complete enrolment and report initial safety and efficacy data. Additionally, the Company is making progress with its solid tumour program targeting CLDN18.2 and looks forward to generating data using the CLDN18.2 CAR in iNKT cells, as well as integrating IL-12-TM. The Company continues to review new technologies for acquisitions that could enhance the CAR-iNKT cell platform or expand its application to target various cancer types. The Company looks forward to providing updates in due course.

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INVESTOR RELATIONS AND NEWS



Dr Michael Baker presents at AusBiotech Invest

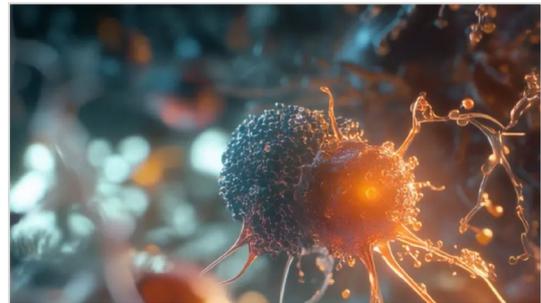
On 21 October, Arovella CEO, Dr Michael Baker, presented at Australia's premier life science investment conference, AusBiotech Invest. Dr Baker described how Arovella's technology provides important advantages over existing T-cell therapies and has the potential to be applied to both blood cancers and solid tumours.

[View presentation](#)

The Australian biotechs racing toward the next billion dollar cancer drug

In November, Arovella CEO, Dr Michael Baker, was interviewed for a Forbes Australia article about the company's iNKT cell therapy.

[View article](#)



Investor presentation

In November, Arovella CEO, Dr Michael Baker, provided an update to investors in the form of a non-deal roadshow in Sydney, Melbourne, Hong Kong and Singapore.

[View presentation](#)

Jumar Showcase

On 20 November, Arovella CEO, Dr Michael Baker, presented at the annual Jumar Showcase. The evening began with a pre-event investor meet & greet, followed by Jumar resident presentations.



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AU CAR-T Showcase

On 25 November, Arovella CEO, Dr Michael Baker, spoke at the Sydney AU CAR-T Showcase. The event was hosted by Monsoon Communications. Dr Baker shared how the company is advancing ALA-101 & a strong CAR-iNKT pipeline targeting blood & solid cancers.

[View presentation](#)

This announcement has been authorised for release by the Company's Board of Directors.

For further information, please contact:

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NOTES TO EDITORS:**About Arovella Therapeutics Ltd**

Arovella Therapeutics Ltd (ASX: ALA) is a biotechnology company focused on developing its invariant natural killer T (iNKT) cell therapy platform from Imperial College London to treat blood cancers and solid tumours. Arovella's lead product is ALA-101. ALA-101 consists of CAR19-iNKT cells that have been modified to produce a Chimeric Antigen Receptor (CAR) that targets CD19. CD19 is an antigen found on the surface of numerous cancer types. Arovella is also expanding into solid tumour treatment through its CLDN18.2-targeting technology licensed from Sparx Group. iNKT cells also contain an invariant T cell receptor (iTTCR) that targets α -GalCer bound CD1d, another antigen found on the surface of several cancer types. ALA-101 is being developed as an allogeneic cell therapy, which means it can be given from a healthy donor to a patient.

Glossary: **iNKT cell** – invariant Natural Killer T cells; **CAR** – Chimeric Antigen Receptor that can be introduced into immune cells to target cancer cells; **TCR** – T cell receptors are a group of proteins found on immune cells that recognise fragments of antigens as peptides bound to MHC complexes; **B-cell lymphoma** – A type of cancer that forms in B cells (a type of immune system cell); **CD1d** – Cluster of differentiation 1, which is expressed on some immune cells and cancer cells.

For more information, visit www.arovella.com

This announcement contains certain statements which may constitute forward-looking statements or information ("forward-looking statements"), including statements regarding negotiations with third parties and regulatory approvals. These forward-looking statements are based on certain key expectations and assumptions, including assumptions regarding the actions of third parties and financial terms. These factors and assumptions are based upon currently available information, and the forward-looking statements herein speak only of the date hereof. Although the expectations and assumptions reflected in the forward-looking statements are reasonable in the view of the Company's directors and management, reliance should not be placed on such statements as there is no assurance that they will prove correct. This is because forward-looking statements are subject to known and unknown risks, uncertainties and other factors that could influence actual results or events and cause actual results or events to differ materially from those stated, anticipated or implied in the forward-looking statements. These risks include but are not limited to: uncertainties and other factors that are beyond the control of the Company; global economic conditions; the risk associated with foreign currencies; and risk associated with securities market volatility. The Company assumes no obligation to update any forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements, except as required by Australian securities laws and ASX Listing Rules.

Appendix 4C

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

Name of entity

Arovella Therapeutics Limited

ABN

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Quarter ended ("current quarter")

31 December 2025

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(1,878)	(3,331)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(28)	(64)
(d) leased assets	-	-
(e) staff costs	(663)	(1,425)
(f) administration and corporate costs	(249)	(728)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	171	416
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	3,209
1.8 Other (GST)	108	215
1.9 Net cash from / (used in) operating activities	(2,540)	(1,709)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	(45)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (Security deposits)	-	(1)
2.6	Net cash from / (used in) investing activities	-	(46)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	302
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(6)	(24)
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	-	-
3.10	Net cash from / (used in) financing activities	(6)	278

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	21,943	20,877
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,540)	(1,709)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(46)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(6)	278
4.5	Effect of movement in exchange rates on cash held	(30)	(34)
4.6	Cash and cash equivalents at end of period	19,367	19,367

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	1,606	1,203
5.2	Call deposits	17,761	20,740
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)	19,367	21,943

6.	Payments to related parties of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	154
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.</i>		
The amount at 6.1 includes Director fees for Non-Executive Directors and salary (including superannuation) for the CEO and Managing Director.		

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

7. Financing facilities	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<i>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.</i>		
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 Total financing facilities	-	-
7.5 Unused financing facilities available at quarter end		-
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.		

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(2,540)
8.2 Cash and cash equivalents at quarter end (item 4.6)	19,367
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	19,367
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	7.6
<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>	
8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
Answer: N/A	
8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?	
Answer: N/A	
8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?	
Answer: N/A	
<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.

23 January 2026

Date:

Board of Directors

Authorised by:
(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.