arovella
THERAPEUTICS

Quarterly Activities & Cash Report and 4C

31 March 2023

Arovella Therapeutics Limited
ABN 35 090 987 250

ASX Release

24 April 2023

APPENDIX 4C: THIRD QUARTER FY 2023

MELBOURNE, AUSTRALIA 24 April 2023: Arovella Therapeutics Ltd (ASX: ALA), a biotechnology company focused on developing its invariant Natural Killer T (iNKT) cell therapy platform for cancer treatment, today releases its Appendix 4C for the third quarter of FY 2023.

During the quarter, Arovella continued to advance its iNKT cell therapy towards first-in-human clinical trials. Arovella's technology provides key advantages over existing CAR-T cell therapies and has the potential to be applied to both blood cancers and solid tumours.

In particular, Arovella:

- Generated exciting new data for its lead product, ALA-101, and had the data accepted for presentation at the American Association for Cancer Research (AACR) Annual Meeting.
    - The data indicate that ALA-101 has the potential to be a novel 'off-the-shelf' cell therapy to treat CD19-expressing leukemias and lymphomas.
- Generated promising *in vitro* data for ALA-101 in combination with Imugene's CF33 oncolytic virus and progressed the joint research program to *in vivo* testing.
- Strengthened its leadership team with the appointment of a new Board Chair and key members of management team.
- Completed an oversubscribed Placement to raise $1.65 million.

In April 2023, Arovella:

- Presented the Company's first poster at the AACR Annual Meeting
- Held an Explanatory Webinar to provide investors with a detailed overview of the iNKT cell therapy platform and the potential of its lead asset, ALA-101, as a novel, off-the-shelf, treatment for blood cancers

Over the next 6-18 months, Arovella expects to achieve several key milestones. These include:

- Scaling-up the manufacturing process for ALA-101 ready for cGMP production
- Manufacturing clinical-grade ALA-101 for a Phase 1 clinical trial
- Commencing a Phase 1 clinical trial with ALA-101 for Non-Hodgkin's Lymphoma
- Completing proof of concept studies and commence IND-enabling studies for ALA-101 + onCARlytics
- Completing CAR-optimisation for IND enabling studies for ALA-104

NEW DATA PRESENTED AT AACR ANNUAL MEETING

In February, Arovella was accepted to present a poster at the American Association for Cancer Research's (AACR) Annual Meeting held in April 2023. The AACR is the first and largest cancer research organization and to be accepted to present is an honour and recognition of the exciting potential of the iNKT cell platform. The data presented supported the manufacturing process licensed from Imperial College London and that the iNKT cell platform, particularly ALA-101, is a promising weapon in the fight against cancer. Specifically:

- iNKT cells could be well expanded (~5000-fold) during manufacture, and cryopreserved (frozen) for future use, without compromising the potency of the cells.
- ALA-101 effectively killed tumour cells that express CD19, including primary patient-derived tumour cells.
- ALA-101 significantly extended the lifespan of mice transplanted with aggressive human B-Cell Acute Lymphoblastic Leukemia (B-ALL) that does not produce CD1d, indicating the activity of ALA-101 through the engineered CD19 CAR.
- Following ~5,000-fold increase in cell numbers during manufacture, CAR19-iNKT cells retained the ability to multiply further when exposed to tumour cells that express CD19.
- The data confirmed that the proposed manufacturing process maintained the effectiveness of the ALA-101 cells when used 'off-the-shelf' after thawing.

The poster was presented at the conference in Orlando, Florida, on April 16th (EDT) by Dr. Mini Bharathan, Arovella's Senior VP of Development and Translational Medicine.

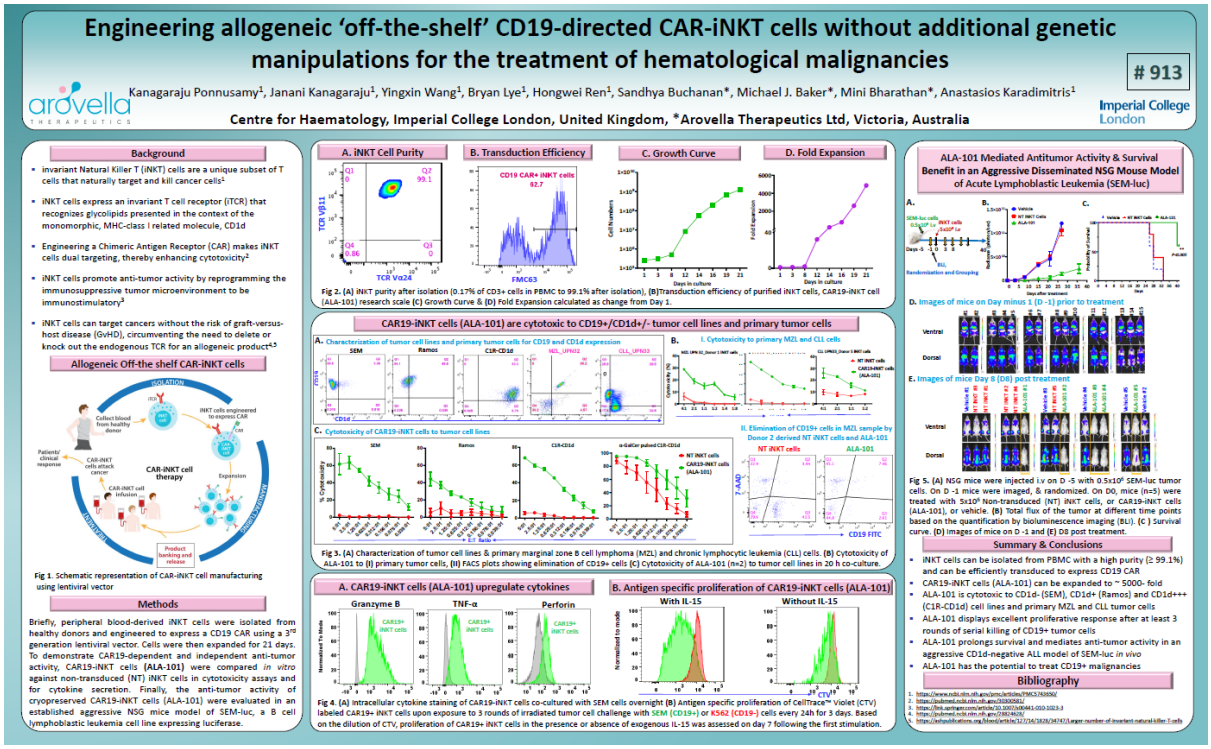

Figure 1. Poster presented at AACR Annual Meeting. A copy of the poster is available on the Company's website: https://www.arovella.com/conference-presentations.

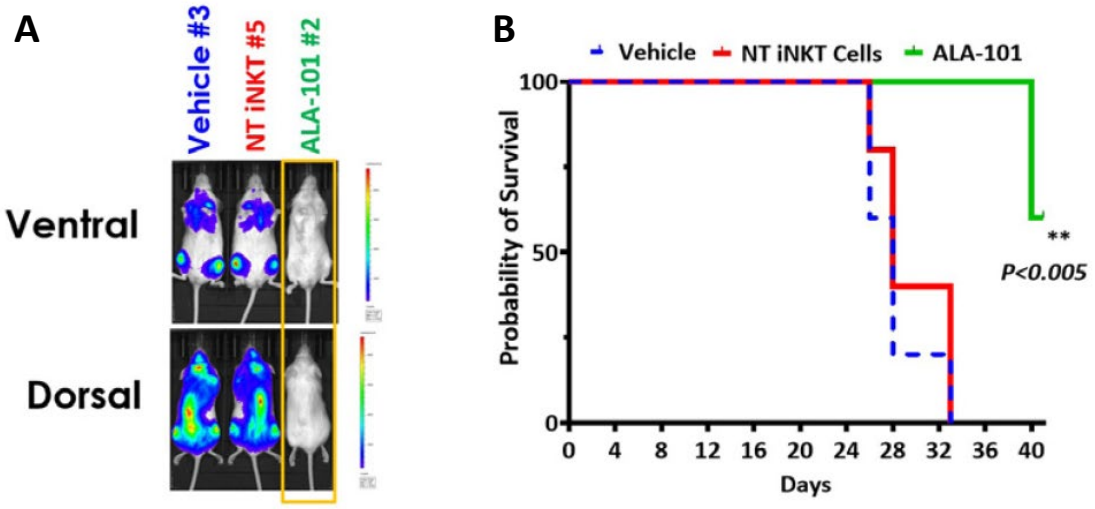

Figure 2. Activity of ALA-101 in mouse model of human B-Cell Acute Lymphoblastic Leukemia (B-ALL). NSG mice were transplanted with an aggressive form of B-ALL before being treated with ALA-101 (green), unmodified iNKT cells (NT-iNKT, red) or a Vehicle control (blue). Animals treated with ALA-101 had on average 90% lower tumour burden than control animals (A, colour represents bioluminescence of tumour cells in imaged mice at 8 days post-treatment) and significantly better survival (B, animal survival over the duration of the study).

STRATEGIC COLLABORATION WITH IMUGENE PROGRESSES

In February, Arovella announced that its research collaboration with clinical-stage immune-oncology company, Imugene (ASX: IMU) would be progressing to the next stage of testing. This was based on positive initial results demonstrating that Arovella's CAR19-iNKT cell therapy (ALA-101) worked in combination with Imugene's onCARlytics platform (CF33) to kill solid tumour cells *in vitro*.

Imugene's onCARlytics platform induces solid tumour cells to express CD19 on their surface, allowing them to be targeted by therapies such as ALA-101, that targets cancer cells through CD19. Solid tumours represent 90% of diagnosed cancer cases[i]; as of 2021, the solid tumour market was valued at US$210 billion[ii].

STRENGTHENING THE LEADERSHIP TEAM

Dr. Tom Duthy – Non-Executive Chair

On 13 March 2023, Arovella announced that Dr. Thomas Duthy had been appointed as Arovella's Non-Executive Chair. Dr. Duthy has over 18 years of direct financial market and executive-level/Board experience with ASX listed companies. He is a Director and Founder of Nemean Group, which provides corporate advisory and investor relations (IR) services in the Life Sciences and Technology sectors. This included an IR/Corporate Development consultancy role with Nova Eye Medical (ASX:EYE), during which time a $100 million all-cash sale of their Lasers & Ultrasound business to Lumibird Group was completed (2020) and a subsequent $61 million return made to shareholders.

Dr. Duthy was the former Head of Corporate Development and IR at Sirtex Medical (ASX:SRX), and was an integral part of the negotiating team that saw its sale to CDH Investments for 1.9 billion dollars in 2018, still the largest medical device acquisition in Australian corporate history. Dr. Duthy is currently an Executive Director of Invex Therapeutics Ltd (ASX:IXC) and Neurotech International Ltd (ASX:NTI),

and will continue his involvement with Nemean Group. Dr. Duthy spent ten years with Taylor Collison, focussing on the sales side for small cap Healthcare and Biotechnology companies. He has significant experience in value-accretive M&A transactions that add substantial value to all shareholders, which will serve Arovella well as we grow our value over time.

In a demonstration of support for the iNKT technology, Dr. Duthy has elected to receive shares *in lieu* of cash for his entire first year of Director fees that would otherwise accrue. These shares will be issued (subject to shareholder approval) at a 29% premium to the 10 day volume-weighted average price prior to his appointment.

Dr. Nicole van der Weerden – Chief Operating Officer

On 4 January 2023, Arovella announced that Dr Nicole van der Weerden has been appointed to the role of Chief Operating Officer. Dr van der Weerden brings over 15 years of strong leadership experience in the biotechnology industry, driving business objectives including pre-clinical discovery, proof-of-concept, manufacturing, and clinical development, and was previously Chief Operating Officer of ASX-listed biotechnology company, Hexima Limited. Dr van der Weerden holds a PhD in biochemistry from La Trobe University and an MBA from Melbourne Business School and is a graduate of the Australian Institute of Company Directors.

Dr. Robson Dossa – Senior Director of Manufacturing and Quality

In March, Arovella appointed Dr. Robson Dossa to the role of Senior Director of Manufacturing and Quality. Dr. Dossa is an exciting addition to the team, having worked at Kite Pharma and Instil Bio where he helped develop and implement GMP manufacturing processes for multiple cell therapy programs currently in clinical trials. Dr. Dossa led technology and knowledge transfers and was involved in the preparation of multiple INDs through the FDA. Dr. Dossa holds a PhD in immunology and during his PhD focused on the potential therapeutic benefits of iNKT cells. Dr. Dossa's strong background in cell therapy manufacturing sets Arovella up for success during scale-up of its manufacturing process ahead of cGMP production and clinical trials.

INVESTOR PRESENTATIONS

Arovella participated in several investor events during the quarter and in early April held an Explanatory Webinar to describe the important benefits of iNKT cells for cell therapy applications and the benefits of Arovella's proprietary manufacturing platform. The webinar can be viewed by clicking on the image below or using the following link: https://www.youtube.com/watch?v=NopK25X6YXI.

In March, Arovella also participated in the NWR Virtual Healthcare Conference. The presentation can be viewed by clicking the image below or using the link: https://www.youtube.com/watch?v=ijaWS7_RI_A&t=2s.

FINANCIAL UPDATE

The net cash used in operating activities during the quarter was $1.83 million compared with $0.75 million for the previous quarter to 31 December 2022. The total of $1.52 million for research and development and staff costs represent approximately 83% of the cash used in operating activities.

In January, the Company raised $1.65 million in a Placement to institutional and sophisticated investors at an issue price of 2 cents per Share. The Placement included participation from Arovella's largest investor, Merchant group, and participation from the Directors of the Company.

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, remuneration and superannuation at commercial rates.

For and on behalf of the Board and 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 is also expanding its DKK1-peptide targeting technology licenced from MD Anderson and used in conjunction with its iNKT cell therapy platform. 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.

iNKT cells also contain an invariant T cell receptor (iTCR) 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; **aGalCer** – alpha-galactosylceramide is a specific ligand for human and mouse natural killer T cells. It is a synthetic glycolipid.

The Company is also commercialising ZolpiMist™ to treat short-term insomnia.

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.

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[i] https://www.cancer.gov/types/common-cancers
[ii] https://www.databridgemarketresearch.com/reports/global-solid-tumors-market#:~:text=Data%20Bridge%20Market%20Research%20analyses,period%20of%202022%20to%202029.

Appendix 4C

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

Name of entity	
Arovella Therapeutics Limited	
ABN	**Quarter ended ("current quarter")**
35 090 987 250	31 March 2023

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (9 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	19	264
1.2	Payments for		
	(a) research and development	(1,063)	(3,037)
	(b) product manufacturing and operating costs	(6)	(114)
	(c) advertising and marketing	(71)	(209)
	(d) leased assets	-	-
	(e) staff costs	(452)	(1,382)
	(f) administration and corporate costs	(342)	(1,198)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	11	23
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	1,049
1.8	Other (provide details if material)	72	200
1.9	**Net cash from / (used in) operating activities**	**(1,832)**	**(4,404)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	65	65
	(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**	**65**	**65**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	1,610	1,614
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	(111)	(117)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**1,499**	**1,497**

+4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	3,512	6,071
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,832)	(4,404)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	65	65

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1,499	1,497
4.5	Effect of movement in exchange rates on cash held	6	21
4.6	**Cash and cash equivalents at end of period**	**3,250**	**3,250**

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	3,250	3,512
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)**	**3,250**	**3,512**

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	165
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.

The amount at 6.1 includes payment of director's fees and salaries and consulting fees, excluding GST where applicable.

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 $A'000**	**Amount drawn at quarter end $A'000**
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.

N/A

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,832)
8.2	Cash and cash equivalents at quarter end (item 4.6)	3,250
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	3,250
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	1.8

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: The Company has and expects that it will continue to have the current level of net operating cash flows. The Board will continue to monitor the cash position closely.

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: In addition to its cash on hand, Arovella has an eligible R&D Tax Incentive receivable of >$1.027 million and the ability to borrow up to 80% of this amount. The Company has commenced the process to obtain access to this funding.

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: Yes, the Company considers it has sufficient funding to continue its operations and meet its business objectives on the basis that, in addition to its cash on hand, it can obtain early access to cash via borrowing against its R&D Tax Incentive receivable.

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

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: 24 April 2023

Authorised by: The Board of Directors
(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.