

December 2023 Activities Report and Appendix 4C

Key points:

- **Cash balance of \$18.4 million with spending in line with budget**
- **PTX-100 Phase 1b study presented at major hematology conference**
- **Excellent safety profile, with no drug-related SAEs**
- **Preliminary efficacy observed in r/r TCL patients exceeding threshold to advance the study**
- **Cell therapy platform development ongoing**
- **Presentation and participation in major scientific and partnering conferences**

MELBOURNE Australia, 31 January 2024: Prescient Therapeutics (ASX: PTX), a clinical stage oncology company developing personalised therapies for cancer, today reported its Appendix 4C quarterly cash flow statement and accompanying Activities Report for the December 2023 quarter.

Financial summary

Prescient ended the quarter with cash reserves of \$18.4 million (\$18.7 million on 30 September 2023) of which \$12.0 million was held in term deposits with maturities of between six and 12 months. Net cash used in operating activities during the quarter was \$0.3 million, in line with budget. A total of \$1.8 million was invested in R&D and clinical development activities.

An R&D Tax Incentive Rebate of \$2.4 million was also received during the period.

The business is operating with a cash runway of 6.63 quarters based on cash used during the quarter, however, Prescient expects the actual cash runway extends beyond this. Payments to related parties of the entity and their associates amounted to \$175,000 and were directly related to non-executive director fees, executive director salary and superannuation.

PTX-100 Phase 1b trial data presented at prestigious ASH Meeting

By far the most significant activity during the reporting period, and a significant milestone in the history of the Company, was the announcement of results of the Phase 1b study of PTX-100 in patients with advanced malignancies, with a focus on patients with relapsed and refractory T-cell lymphomas (r/r TCL). The results were presented at the prestigious American Society of Hematology (ASH) Annual Meeting in San Diego, California last month.

TCLs are a group of lymphomas that occur when T-cells become cancerous. It is an orphan disease, with a prevalence of 90,275 cases in the eight major markets in 2020¹. TCLs represent an area of high unmet medical need and poor patient outcomes.

Aims and design

The aim of this Phase 1 study was to evaluate the safety, PD and PK and preliminary efficacy of PTX-100 administered in increasing doses in patients with advanced malignancies, with an expansion cohort in r/r TCL. Recruitment took place at Epworth under the leadership of Principal Investigator and international lymphoma expert, Professor H. Miles Prince, AM.

This Phase 1b consists of a 3+3 dose escalation at doses of 500, 1000 and 2000 mg/m² PTX-100. PTX-100 is administered by intravenous infusion over 60 minutes on days 1 to 5 of a 14 day cycle for 4 cycles. Disease response is assessed after 4 cycles and patients with a complete response (CR), partial response (PR) or stable disease (SD) may be eligible for continued treatment with PTX 100, dosed in 21 day cycles with response assessment every 3 months.

Safety

PTX-100 was well tolerated at all doses. Physicians reported that there were no serious adverse events that were related to PTX-100. Overall, PTX-100 has exhibited an excellent safety profile, especially in light of the fragile patient population and the relatively high toxicities of many approved therapies for r/r TCL.

Efficacy

Efficacy was determined by follow-up scans at the end of cycle 4 of treatment (C4). Nine TCL patients were determined to be evaluable for efficacy at the time of the ASH Meeting. Two r/r PTCL patients and two r/r CTCL patients had clinical responses, including two r/r PTCL patients with CRs (complete eradication of disease), for an overall response rate (ORR) of 4/9, or 44%. Additionally, two CTCL patients had durable stable disease (SD) greater than 6 months, for a clinical benefit rate of 6/9, or 66%. Prescient and its investigators consider an ORR over 30% and a CBR over 45% to be promising for a drug in r/r TCL.

¹ GlobalData. Eight major markets include US; France; Germany; Italy; Spain; Japan and China

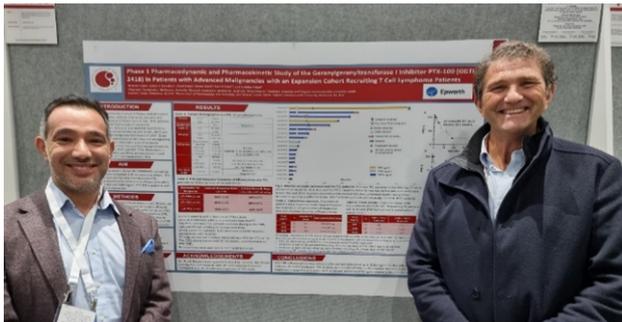
Evaluable for Response	Overall Response Rate	Clinical Benefit Rate
	CR + PR	CR + PR + SD>6months
Benchmark²	30%	45%
r/r PTCL (n=4)	50% (2/4)	50% (2/4)
r/r CTCL (n=5)	40% (2/5)	80% (4/5)
r/r TCL (n=9)	44% (4/9)	66% (6/9)

Durations of responses demonstrated a median PFS of 12.2 months for all assessable r/r TCL patients; 13.6 month for r/r CTCL and 7.4 months for r/r PTCL. For context, several key opinion leaders consider that a benchmark median PFS for a registration study in r/r TCL is 5-6 months³.

Clinical data well received at ASH

These results were presented at the prestigious ASH Annual Meeting by Professor Prince last month in San Diego, California. ASH is the largest and most comprehensive hematology conference in the world, where international physicians, industry participants and researchers gather to discuss the latest advancements and innovations in haematological diseases.

Industry participants and key opinion leaders responded very positively to the PTX-100 data in r/r TCL. They noted it compared favourably with currently available and emerging therapies.



In addition to robust efficacy, PTX-100's safety profile was acknowledged as a distinguishing feature, which could also make it a viable option for exploring future combination therapies.

² Considered a target benchmark by Prescient and its investigators, with reference to currently available therapies in r/r TCL

³ S.M. Horowitz *et al*; Blood. Dec 2021

For comparison, two other posters at ASH on similar sized r/r TCL trials reported the following data. PTX-100 compares very favourably:

	Size	ORR	mPFS
PI3K γ δ DNA-PK triple inhibitor	n=19	31%	5.6 months
GemDox (chemo)	n=18	50%	5 months
PTX-100	n=19	44%	12.2 months

Preparation for Phase 2 trial

The PTX-100 Phase 1b safety and ORR data has exceeded the threshold required to advancing this promising agent. Prescient is currently incorporating useful insights from key opinion leaders in the field of TCL on the Phase 2 protocol synopsis and related clinical trial matters. Prescient intends to meet with the FDA in Q2 2024 to discuss the Phase 2 trial design and the potential for accelerated approval. It is worth highlighting that any such feedback from the FDA on accelerated approval is likely to be indicative and will ultimately depend on the Phase 2 results. Prescient is aiming for the Phase 2 study to commence around the middle of 2024 although FDA input will be critical to estimating the timing.

Simultaneously, Prescient's manufacturing campaign of PTX-100 to support this upcoming trial is running to schedule, with timely delivery expected of active pharmaceutical ingredient. Chemistry, Manufacturing, and Control (CMC) resources in the US continue to be bolstered to support this important effort. Additionally, considerable work is required to document CMC for regulatory purposes to a standard required of more advanced clinical programs. This substantial and crucial work is also underway.

Cell therapy platform development

OmniCAR

Platform optimisation of OmniCAR is progressing, to investigate unarmed T-cell activity and improving control features. As a unique and multi-modal platform, this program is involving domain experts across protein and cell engineering and other areas. Prescient maintains the view that modularity can play a transformative role in cell therapies, and that this development will position OmniCAR favourably for when the cell therapy sector regains buoyancy.

CellPryme

CellPryme is nearing completion of pre-clinical development in enhancing CAR-T cell therapies. In 2023, Prescient developed deep insights into the manufacturing and trial needs and limitations of the cell therapy sector in an intense period of business development activity and industry engagement. CellPryme-M has a substantially lower hurdle to integrate in partner programs, especially for those programs still in preclinical development. Potential partners already in the clinic may be reticent to change their manufacturing protocols mid-stream (at least unless they encounter problems that CellPryme-M can solve). CellPryme-A is a higher value opportunity that requires a higher hurdle to integrate but can augment clinical-ready opportunities.

Prescient is preparing regulatory packages for both CellPryme-M and CellPryme-A and is seeking to enter clinical trials with partners and collaborators.

Maintaining engagement with international biotech sector

Prescient presented at key scientific and biotech industry conferences to maintain industry engagement and to update potential partners and collaborators, despite this being a time of sector challenges. During the reporting period, Prescient participated in the Cell and Gene Meeting on the Mesa; BIO Europe and the ASH Annual Meeting. At each event, despite subdued industry activity, Prescient continued to receive positive feedback on its data and development progress.

Significant value inflexion points

The company is eagerly looking ahead to crucial clinical and developmental milestones in the coming quarters, heralding a period of significant value inflexion, namely seeking agreement with the FDA on trial design in Q2; and commencement of the Phase 2 study in TCL scheduled for mid-2024. This study will be the culmination of many years of hard work from pre-clinical research, clinical development, and CMC. With a solid financial foundation, an outstanding team across all essential business functions, and a valuable, diversified pipeline of cancer therapies yielding compelling data, Prescient is very optimistic.

The entire team at Prescient is genuinely excited and dedicated to delivering pioneering cancer therapies, especially for individuals facing challenging-to-treat cancers. The future appears very promising, and the team's commitment to making a positive impact in the field of cancer treatment remains steadfast.

- Ends -

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About Prescient Therapeutics Limited (Prescient)

Prescient Therapeutics (ASX: PTX) is a clinical stage oncology company developing personalised medicine approaches to cancer, including targeted and cellular therapies.

Targeted Therapies

PTX-100 is a first in class compound with the ability to block an important cancer growth enzyme known as geranylgeranyl transferase-1 (GGT-1). It disrupts oncogenic Ras pathways by inhibiting the activation of Rho, Rac and Ral circuits in cancer cells, leading to apoptosis (death) of cancer cells. PTX-100 is believed to be the only GGT-1 inhibitor in the world in clinical development. PTX-100 demonstrated safety and early clinical activity in a previous Phase 1 study and recent PK/PD basket study of hematological and solid malignancies. PTX-100 is now in a Phase 1b expansion cohort study in T cell lymphomas, where it is showing encouraging efficacy and safety. The US FDA has granted PTX-100 Orphan Drug Designation for all T Cell Lymphomas.

PTX-200 is a novel PH domain inhibitor that inhibits an important tumour survival pathway known as Akt, which plays a key role in the development of many cancers, including breast and ovarian cancer, as well as leukemia. Unlike other drug candidates that target Akt inhibition, PTX-200 has a novel mechanism of action that specifically inhibits Akt without non-specific kinase inhibition effects. This highly promising compound is currently in a Phase 1b/2 trial in relapsed and refractory AML, where it has resulted in 4 complete remissions so far. PTX-200 previously generated encouraging Phase 2a data in HER2-negative breast cancer and Phase 1b in recurrent or persistent platinum resistant ovarian cancer.

Cell Therapies

CellPryme-M: Prescient's novel, ready-for-the-clinic, CellPryme-M technology enhances adoptive cell therapy performance by shifting T and NK cells towards a central memory phenotype, improving persistence, and increasing the ability to find and penetrate tumours. CellPryme-M is a 24-hour, non-disruptive process during cell manufacturing. Cell therapies that could benefit from additional productivity in manufacturing or increased potency and durability in-vivo, would be good candidates for CellPryme-M.

CellPryme-A: CellPryme-A is an adjuvant therapy designed to be administered to patients alongside cellular immunotherapy to help them overcome a suppressive tumour microenvironment. CellPryme-A significantly decreases suppressive regulatory T cells; increases expansion of CAR-T cells in vivo; increases tumour penetration of CAR-T cells. CellPryme-A improves tumour killing and host survival of CAR-T cell therapies, and these benefits are even greater when used in conjunction with CellPryme-M pre-treated CAR-T cells.

OmniCAR: is a universal immune receptor platform enabling controllable T-cell activity and multi- antigen targeting with a single cell product. OmniCAR's modular CAR system decouples antigen recognition from the T-cell signalling domain. It is the first universal immune receptor allowing post- translational covalent loading of binders to T-cells. OmniCAR is based on technology licensed from Penn; the SpyTag/SpyCatcher binding system licensed from Oxford University; and other assets. OmniCAR is in pre-clinical development.

The targeting ligand can be administered separately to CAR-T cells, creating on-demand T-cell activity post infusion and enables the CAR-T to be directed to an array of different tumour antigens. OmniCAR provides a method for single-vector, single cell product targeting of multiple antigens simultaneous or sequentially, whilst allowing continual re-arming to generate, regulate and diversify a sustained T-cell response over time.

Find out more at www.ptxtherapeutics.com or connect with us via Twitter [@PTX_AUS](#) and [LinkedIn](#).



The Board of Prescient Therapeutics Limited has approved the release of this announcement.

For more information please contact:

Company enquiries

Steven Yatomi-Clarke
CEO & Managing Director
Prescient Therapeutics
steven@ptxtherapeutics.com

Investor enquiries

Ally Leiba
Reach Markets
1300 805 795
ir@reachmarkets.com.au

Media enquiries

Andrew Geddes
CityPR
+61 2 9267 4511
ageddes@citypublicrelations.com.au

Disclaimer and Safe Harbor Statement

Certain statements made in this document are forward-looking statements within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These forward-looking statements are not historical facts but rather are based on the current expectations of Prescient Therapeutics Limited ("Prescient" or the "Company"), their estimates, assumptions, and projections about the industry in which Prescient operates. Material referred to in this document that use the words 'estimate', 'project', 'intend', 'expect', 'plan', 'believe', 'guidance', and similar expressions are intended to identify forward-looking statements and should be considered an at-risk statement. These forward-looking statements are not a guarantee of future performance and involve known and unknown risks and uncertainties, some of which are beyond the control of Prescient or which are difficult to predict, which could cause the actual results, performance, or achievements of Prescient to be materially different from those which may be expressed or implied by these statements. These statements are based on our management's current expectations and are subject to a number of uncertainties and risks that could change the results described in the forward-looking statements. Risks and uncertainties include, but are not limited to, general industry conditions and competition, general economic factors, global pandemics and related disruptions, the impact of pharmaceutical industry development and health care legislation in the United States and internationally, and challenges inherent in new product development. In particular, there are substantial risks in drug development including risks that studies fail to achieve an acceptable level of safety and/or efficacy. Investors should be aware that there are no assurances that results will not differ from those projected and Prescient cautions shareholders and prospective shareholders not to place undue reliance on these forward-looking statements, which reflect the view of Prescient only as of the date of this announcement. Prescient is not under a duty to update any forward-looking statement as a result of new information, future events or otherwise, except as required by law or by any appropriate regulatory authority.

Certain statements contained in this document, including, without limitation, statements containing the words "believes," "plans," "expects," "anticipates," and words of similar import, constitute "forward-looking statements." Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results, performance or achievements of Prescient to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Such factors include, among others, the following: the risk that our clinical trials will be delayed and not completed on a timely basis; the risk that the results from the clinical trials are not as favourable as we anticipate; the risk that our clinical trials will be more costly than anticipated; and the risk that applicable regulatory authorities may ask for additional data, information or studies to be completed or provided prior to their approval of our products. Given these uncertainties, undue reliance should not be placed on such forward-looking statements. The Company disclaims any obligation to update any such factors or to publicly announce the results of any revisions to any of the forward-looking statements contained herein to reflect future events or developments except as required by law.

This document may not contain all the details and information necessary for you to make a decision or evaluation. Neither this document nor any of its contents may be used for any other purpose without the prior written consent of the Company.

Supplemental COVID-19 Risk Factors

Please see our website: [Supplemental COVID-19 Risk Factors](#)

Appendix 4C

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

Name of entity

Prescient Therapeutics Limited

ABN

56 006 569 106

Quarter ended ("current quarter")

31 December 2023

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	(1,886)	(4,317)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(297)	(568)
(f) administration and corporate costs	(591)	(1,123)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	126	163
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	2,368	2,368
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(280)	(3,477)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(g) entities	-	-
(h) businesses	-	-
(i) property, plant and equipment	(1)	(1)

Appendix 4C
Quarterly cash flow report for entities subject to Listing Rule 4.7B

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
(j) investments in term deposits with maturities longer than 3 months at acquisition	-	-
(k) intellectual property	-	-
(l) other non-current assets	-	-
2.2 Proceeds from disposal of:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments *	4,000	4,000
(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	3,999	3,999

* The proceeds from disposal of investments were in relation to \$4 million a term deposit with maturity term of 6 months, and were classified in the statement of financial position as short-term investments in accordance with AASB.

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	-	18
3.4 Transaction costs related to issues of equity securities or convertible debt securities	-	-
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	-	18

Appendix 4C
Quarterly cash flow report for entities subject to Listing Rule 4.7B

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	2,708	5,895
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(280)	(3,477)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	3,999	3,999
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	18
4.5	Effect of movement in exchange rates on cash held	(10)	(18)
4.6	Cash and cash equivalents at end of period	*6,417	*6,417

* In addition to the cash and cash equivalents balance above as at 31 December 2023, the Company holds an additional \$12 million in term deposits with maturity terms ranged between 6 months and 12 months (30 September 2023: \$16 million), classified in the statement of financial position as short-term investments in accordance with AASB.

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	4,417	2,708
5.2	Call deposits	2,000	-
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)	**6,417	**2,708

*The call deposits included in item 5.2 above, have maturities ranged between 1 month and 3 months at 31 December 2023.

** In addition to the cash and cash equivalents balance above as at 31 December 2023, the Company holds an additional \$12 million in term deposits with maturity terms ranged between 6 months and 12 months (30 September 2023: \$16 million), classified in the statement of financial position as short-term investments in accordance with AASB.

Appendix 4C
Quarterly cash flow report for entities subject to Listing Rule 4.7B

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	175
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.

7. Financing facilities <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>	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.		

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(280)
8.2 Cash and cash equivalents at quarter end (item 4.6)	6,417
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	*6,417
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	*22.9
<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>	
<i>* In addition to the cash and cash equivalents balance noted above at 8.4, the Company holds an additional \$12 million in term deposits, classified in the statement of financial position as short-term investments in accordance with AASB, due to the maturity date being greater than 3 months. As a result, the estimated quarters of funding available will be greater than the figure provided in 8.5 due to holding these additional short-term investments. On a pro-forma basis with the \$16 million included, the Company would have estimated quarters of funding available amounting to 5.9.</i>	
8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions: N/A	
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?	
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?
	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?
	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.

Date: 31 January 2024

Authorised by: By the Board
(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.