

## Quarterly Activities Report for the period ending 31 March 2024

**Neurotech International Limited (ASX: NTI)** ('Neurotech', 'NTI' or 'the Company') a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, is pleased to present its activities report for the quarter ended 31 March 2024 (Q3 FY24), together with its Appendix 4C Quarterly Cash Flow Report.

### CLINICAL UPDATES

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#### Autism Spectrum Disorder

On 7 February 2024, the Company provided an update on the progress of the 11 autism spectrum disorder (ASD) patients who were part of the Company's world-first Phase I/II clinical trial examining the daily use of Neurotech's proprietary broad spectrum cannabinoid drug therapy, NTI164 out to 52 weeks of treatments, as initially announced in March 2023.

All patients have crossed 90 weeks of daily oral therapy with NTI164. Neurotech reported that NTI164 continued to exhibit an exceptional safety and tolerability profile, with all patients showing stable blood chemistries and normal liver and kidney function over 90 weeks. This is the longest ever study in ASD examining the safety of a broad-spectrum cannabinoid drug treatment.

The Company received qualitative feedback from parents/caregivers on their child's ASD, as quoted below.

A parent of one paediatric participant who has continued treatment past 90 weeks said:

***"We are so privileged to be a part of a revolutionary study that has enabled our child to participate in everyday activities which would have been very stressful and almost impossible to do in the past. To be able to participate in school sports and camp is something we never imagined we could achieve. We are very grateful."***

A second parent of a patient on the extension study commented:

***"The impact of our son's autism has had a profound impact on our family unit. We have had to cut back on our career's, our social events, holidays and basic everyday activities. To be able to participate in a study that has not only enhanced our son's quality of life but has also improved our lives as a family unit is remarkable in every sense."***

Professor Michael Fahey, Head of the Paediatric Neurology Unit at Monash Medical Centre, Director of Neurogenetics and Chief Investigator of the NTI164 Phase I/II Trial said:

***"I am delighted with the progress of my patients under this long term extension to our original Phase I/II clinical trial, which sought to examine the safety and efficacy of NTI164 following 30 days of daily oral therapy. To have 11 patients still on treatment past 90 weeks is testament to the durable responses we have seen in our patients coupled with a remarkable safety profile of this intervention in Level 2 and 3 autism patients. We therefore eagerly await the results of the double-blind, placebo-controlled Phase II/III clinical trial to confirm these earlier clinical findings."***

On 13 February 2024, Neurotech announced Human Research Ethics Committee (HREC) approval to extend the Phase I/II clinical trial in autism spectrum disorder (ASD) by another 52 weeks in total. The additional 52 week HREC extension for this trial was based on requests from the Company's Lead Investigator, patients and their caregivers, to continue to extend the duration of treatment for these patients.

Professor Michael Fahey, Chief Investigator of the NTI164 Phase I/II Trial said:

***"This second long-term extension to our core clinical program which commenced in mid-2022 and reported 52 week safety and efficacy data in March 2023 reflects the significant progress my patients have made, and their caregivers strong desire to continue treatment over the long term. The lack of side-effects with NTI164 and the significant clinical improvements we've observed in these patients necessitates a long-term treatment plan. We thank Neurotech for their continued support of our early study patients and we look forward to the results of our larger double-blind, placebo-controlled Phase II/III clinical trial in ASD."***

On 17 April 2024, the Company released very strong clinical trial results from the randomised, double-blind, placebo-controlled Phase II/III ASD clinical trial of NTI164 versus placebo in Level II and Level III Autism Spectrum Disorder (ASD) patients. The data is summarised within the Post Quarter Events section, below.

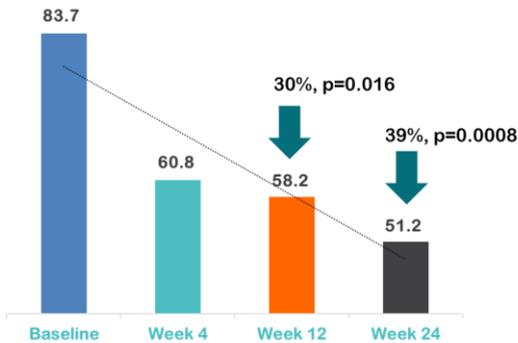
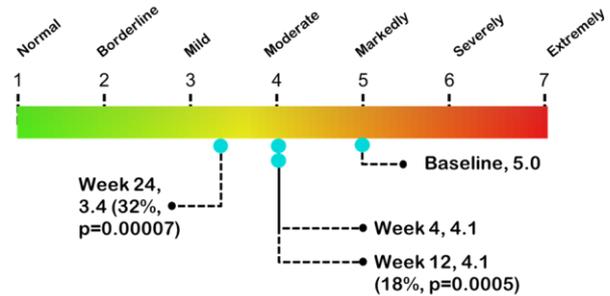
## PANDAS/PANS

On 21 February 2024 the Company provided an update on the open-label Phase I/II clinical trial of NTI164 in children diagnosed with Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS), with all 15 patients entering into the 54 week extension phase of the trial in late August 2023.

As previously reported, NTIPANS1 showed a statistically significant and clinically meaningful improvement shown across a range of gold-standard, clinically validated assessments over 12 weeks of NTI164 treatment.

Data analysis undertaken at 24 weeks has shown continued improvements in patients with no adverse or serious adverse events recorded from 12-24 weeks. In summary:

- NTIPANS1 was the first ever clinical trial to show highly significant clinical improvements in PANDAS/PANS patients (n=15) with a broad-spectrum cannabinoid drug therapy (NTI164) with excellent safety at 12 weeks
- Data analysis demonstrated:
  - more substantial evidence of the clinical utility of NTI164 in PANDAS/PANS with further improvements at 24 weeks v baseline relating to the gold-standard validated measure of anxiety/depression, RCADS-P (39% improvement, p=0.0008 v 30%, p=0.016 at week 12)
  - Severity of illness (CGI-S) continued to improve with patients down-staged from markedly ill at baseline to mildly ill at 24 weeks (32% improvement, p=0.00007), which was a further improvement from 12 weeks versus baseline (18%, p=0.0005)
- There are no approved treatments for PANDAS/PANS, which is an orphan disease and represents an addressable market of US\$1.4 billion annually in the US

**Significant Improvement in anxiety / depression**
**Significant Improvement in Disease Severity**
**RCADS-P (n=15)**

**RCADS-P<sup>1</sup>**
**Severity of illness Scale (CGI-S)(n=15)**

**CGI-Severity of illness<sup>1</sup>**
**Cerebral Palsy**

On 29 January 2024, Neurotech announced Human Research Ethics Committee (HREC) approval and Clinical Trial Notification (CTN) scheme clearance by the Therapeutic Goods Administration (TGA) to commence a Phase I/II clinical trial investigating the use of NTI164 in paediatric patients with Spastic Diplegia Cerebral Palsy (Spastic CP) the most common form of CP, representing up to 80% of cases.

CP is the leading cause of childhood disability. Approximately 750,000 children and adults in the United States have CP. In Australia, there are approximately 34,000 persons living with CP. The market is estimated to grow to US\$4.3 billion annually by 2030.

The Phase I/II trial is proposed to be a single-arm, open-label clinical trial that will recruit up to 14 paediatric patients with a clinical diagnosis of Gross Motor Function Classification System (GMFCS) severity of 2-3, non-ambulant Spastic CP patients to determine the efficacy and safety of NTI164 in these patients from baseline to twelve (12) weeks of treatment with NTI164. The trial intends to enrol patients at Monash Medical Centre. The primary endpoint of the trial is the Caregiver Priorities and Child Health Index of Life with Disabilities (CPCHILD®) Questionnaire, which evaluates caregivers' perceptions of health-related quality of life (HRQOL) and caregiver impact in children with CP.

Secondary endpoints include safety and the effect of NTI164 on pain, sleep, seizure frequency, dystonia (involuntary muscle contraction) and spasticity.

The Lead Investigator of the trial is Professor Michael Fahey, Head of the Paediatric Neurology Unit and Director of Neurogenetics at Monash Medical Centre, Victoria, Australia. Professor Fahey has significant experience with NTI164 having led both Neurotech's Phase I/II and Phase II/III clinical trials in autism.

**Rett Syndrome**

Rett Syndrome is the second leading cause of intellectual disability in girls, with an urgent medical need to develop safe and effective therapies to treat this progressive neurological disease. Rett Syndrome is an orphan disease with no cure and an annual market opportunity estimated at over US\$2 billion<sup>1</sup>.

<sup>1</sup> <https://www.livewiremarkets.com/wires/a-de-risked-biotech-with-4x-upside>

The NTIRT1 Phase I/II clinical trial examined the effects of daily oral treatment of NTI164 in 14 Rett Syndrome patients. During the quarter, Neurotech announced the extension of the Company's Phase I/II clinical trial investigating the use of NTI164 in female Rett Syndrome patients and an additional HREC approval. All 14 Rett Syndrome patients (100% of trial participants) have elected to receive NTI164 for a total of 52 weeks under the extension phase of the Phase I/II clinical trial.

The results of the Phase I/II clinical trial (top-line, primary endpoint analysis only) was released on 17 April 2024 (see below).

## Post Quarter Events

On 10 April 2024, the Company announced the signing of a binding term sheet with Fenix Innovation Group ("Fenix"), a leading contract research organisation ("CRO") based in Melbourne, Australia. Fenix will work exclusively with Neurotech in the medicinal cannabis field with the development of the Company's broad spectrum cannabinoid drug therapy NTI164 for neurological disorders. Fenix has dedicated substantial resources into the various NTI164 programs for Neurotech and has been integral in the development of NTI164 since 2019, efficiently overseeing the manufacturing and preparation of drug product, regulatory submissions, clinical trial protocol development, management of clinical trials and key opinion leader development. The alignment of Neurotech's development objectives with Fenix is expected to result in the execution of Neurotech's overall clinical and commercial development pathways in a much more time and cost effective than would otherwise be the case.

On 17 April 2024, Neurotech announced the results of its Phase II/III ASD clinical trial, positive top-line results from its Phase I/II Rett Syndrome clinical trial and a \$10.0 million capital raise. These milestones are summarised, as follows:

### Autism

- Phase II/III clinical trial met the primary endpoint of a statistically significant improvement in severity of illness (CGI-S) at 8 weeks between NTI164 and placebo ( $p < 0.001$ )
- Children in NTI164 group re-classified from markedly-severely ill at baseline to mild-moderately ill at 8 weeks, a very strong improvement
- Strong improvements in all secondary endpoints: adaptive behaviours (the treatment goal in autism) ( $p = 0.024$ ) and social responsiveness ( $p = 0.028$ )
- Strong drug-related improvements ( $p < 0.001$ )
- No serious adverse events recorded, small number of minor adverse events were low and overall were less in NTI164 arm in comparison to placebo arm
- Neurotech to accelerate registration-related regulatory discussions given strength of data

*Prof Michael Fahey, Lead Investigator:*

***"The analysis so far of the trial, which compared NTI164 to placebo over 8 weeks of daily treatment, have demonstrated statistically significant and clinically meaningful improvements in the severity of illness and adaptive behaviours such as communication and socialisation without any significant side effects. Currently, there are no FDA or TGA-approved treatments that show clinically significant improvements in one or more of autism's three core symptom domains: communication, impaired social interaction, and restricted behaviours. Therefore, the NTIASD2 clinical trial data look promising, given the substantial unmet market need for safe and effective therapies for autism, like NTI164."***

### Rett Syndrome

- NTIRTT1 is the first clinical trial to show a statistically significant clinical improvement in Rett Syndrome patients (n=14) with a broad-spectrum cannabinoid drug therapy (NTI164)
- Primary endpoint of Clinical Global Impression – Improvement (CGI-I) at 12 weeks versus baseline was met; mean improvement of -0.3, (p=0.04)
- CGI-I compares favourably to the only FDA approved Rett Syndrome drug DAYBUE™ (trofinetide) Phase 3 CGI-I data vs placebo in Rett -0.3, 8% improvement (p=0.003)
- Data collection is ongoing with additional analysis on primary endpoint, key secondary endpoints and safety to be available in the next 2-4 weeks

### Capital Raise

- Neurotech received binding commitments for a \$10.0 million Placement with support from existing and new institutional, professional and sophisticated Australian and overseas investors
- Capital raised to be used to accelerate registration-directed activities, fund further clinical trials as required and manufacturing expansion

### Outlook

Neurotech has made excellent progress to date in accelerating the use of NTI164 in a number of paediatric neurological disorders, now having showed statistically significant and clinically meaningful data in three paediatric neurological disorders, two of which are considered rare or “orphan” in nature.

For the remainder of FY24 (to 30 June 2024), Neurotech anticipates:

- Results of Rett Syndrome Phase I/II Clinical Trial – full data (2-4 weeks from 17 April 2024)
- Meeting outcome – TGA Regulatory Advice
- Publications for ASD Phase I/II + pre-clinical NTI164 results
- Metabologenomic data from Phase I/II PANDAS/PANS Clinical Trial

## CORPORATE ACTIVITY

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### Appendix 4C Commentary

During the quarter, the Company recorded total cash operating expenses (excluding revenue sources) of \$1.7 million (Q2 FY2024: \$1.9 million), consisting of research and development \$1.5 million (Q2 FY24: \$1.6 million), along with advertising, marketing, staff costs, administrative, and corporate costs of \$0.26 million (Q2 FY24: \$0.36 million). The Company received a negligible GST refund for the quarter (Q2 FY24: \$0.15 million). Total operating cash outflows for the quarter were \$1.7 million (Q2 FY24: \$1.3 million inflow). R&D investment during the quarter reflected investment into the Phase II/III ASD clinical trial, and Phase I/II clinical trials in Rett Syndrome, along with drug product manufacturing costs. Cash inflow from financing activities of \$1.5 million reflected the exercise of share options during the period.

The Company closed the quarter with cash and cash equivalents of \$4.2 million (Q2 FY24: \$4.5 million).

Further, payments to related parties and their associates as detailed in Section 6 of the Appendix 4C relate to director fees (\$97,000) and corporate services, accounting and company secretarial fees (\$68,000).

## ESG Report

On 26 February 2024, Neurotech released its initial Environmental Social Governance (ESG) Report (also known as the 'Sustainability Report') to accompany the First Half FY2024 results. The Report responds to the 21 core metrics identified by the World Economic Forum (WEF) in its stakeholder capitalism framework. For a small therapeutics Company like Neurotech, ESG principles are crucial for long-term success and sustainability. By integrating ESG considerations into our operations, we believe it can enhance our reputation, attract investors who prioritise responsible investment practices, and mitigate various risks associated with environmental, social, and governance factors.

Neurotech will provide a second report that will accompany its 2024 financial results in August. A copy of the report can be viewed here: <https://www.investi.com.au/api/announcements/nti/122eee74-2be.pdf>

## Authority

This announcement has been authorised for release by the Board of Neurotech International Limited.

## Further Information

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## About Neurotech

**Neurotech International Limited (ASX:NTI)** is a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders. Neurotech has completed a Phase I/II clinical trial in Autism Spectrum Disorder (ASD), which demonstrated excellent safety and efficacy results at 28 days, 20 weeks and 52 weeks of treatment with NTI164. The Company commenced Phase II/III randomised, double-blind, placebo-controlled clinical trial in ASD in Q4 CY2022. Neurotech is also conducting additional Phase I/II trials in Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS), collectively PANDAS/PANS, along with Rett Syndrome and Cerebral Palsy during CY2023. Neurotech is also commercialising Mente, the world's first home therapy that is clinically proven to increase engagement and improve relaxation in autistic children with elevated Delta band brain activity.

For more information about Neurotech and Mente Autism, please visit [www.neurotechinternational.com](http://www.neurotechinternational.com).

## Appendix 4C

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

**Name of entity**

Neurotech International Limited

**ABN**

73 610 205 402

**Quarter ended ("current quarter")**

31 March 2024

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	0	2
1.2 Payments for		
(a) research and development	(1,510)	(5,075)
(b) product manufacturing and operating costs	0	0
(c) advertising and marketing	(33)	(158)
(d) leased assets	0	0
(e) staff costs	(24)	(138)
(f) administration and corporate costs	(202)	(800)
1.3 Dividends received (see note 3)	0	0
1.4 Interest received	28	75
1.5 Interest and other costs of finance paid	(2)	(5)
1.6 Income taxes paid	0	0
1.7 Government grants and tax incentives (R&D Rebate)	0	3,175
1.8 Other (GST refunds)	1	380
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,742)</b>	<b>(2,544)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	0	0
(b) businesses	0	0
(c) property, plant and equipment	0	0
(d) investments	0	0
(e) intellectual property	0	0

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
(f) other non-current assets	0	0
2.2 Proceeds from disposal of:		
(a) entities	0	0
(b) businesses	0	0
(c) property, plant and equipment	0	0
(d) investments	0	0
(e) intellectual property	0	0
(f) other non-current assets	0	0
2.3 Cash flows from loans to other entities	0	0
2.4 Dividends received (see note 3)	0	0
2.5 Other (provide details if material)	0	0
<b>2.6 Net cash from / (used in) investing activities</b>	<b>0</b>	<b>0</b>

<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	0	0
3.2 Proceeds from issue of convertible debt securities	0	0
3.3 Proceeds from exercise of options	1,500	1,760
3.4 Transaction costs related to issues of equity securities or convertible debt securities	0	0
3.5 Proceeds from borrowings	0	0
3.6 Repayment of borrowings	0	0
3.7 Transaction costs related to loans and borrowings	0	0
3.8 Dividends paid	0	0
3.9 Other (provide details if material)	0	0
<b>3.10 Net cash from / (used in) financing activities</b>	<b>1,500</b>	<b>1,760</b>

<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash and cash equivalents at beginning of period	4,479	5,022
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(1,742)	(2,544)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	0	0

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1,500	1,760
4.5	Effect of movement in exchange rates on cash held	(1)	(2)
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>4,236</b>	<b>4,236</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	2,770	2,507
5.2	Call deposits	1,515	2,015
5.3	Bank overdrafts	(49)	(43)
5.4	Other (provide details)	0	0
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>4,236</b>	<b>4,479</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	<b>Current quarter \$A'000</b>
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	0
<p>Payments at section 6. relate to director fees (\$97,000) and corporate services, accounting and company secretarial fees (\$68,000).</p>		

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

<b>7. Financing facilities</b>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
<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	66	(49)
7.2 Credit standby arrangements	0	0
7.3 Other (please specify)	0	0
7.4 <b>Total financing facilities</b>	<b>66</b>	<b>(49)</b>
7.5 <b>Unused financing facilities available at quarter end</b>		<b>17</b>
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>Overdraft facility with a limit of EUR 40,000. The lender is Bank of Valetta. The facility is unsecured. The interest rate is 5.65%.</p> <p>The above values are stated in AUD, converted from EUR at an exchange rate of 0.6059.</p>	

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	1,742
8.2 Cash and cash equivalents at quarter end (item 4.6)	4,236
8.3 Unused finance facilities available at quarter end (item 7.5)	17
8.4 Total available funding (item 8.2 + item 8.3)	4,253
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>2.44</b>
<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?	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: 23 April 2024  
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Authorised by: The Board of Directors  
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(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.