# ASX Announcement

28/04/2021

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## Emyria forms strategic partnership to accelerate EMD-003, expands clinics, boosts advisory team and wins digital health grant

**Emyria Limited (ASX: EMD)** (Emyria or the Company), a data-backed drug development company, is proud to share this report on the Company's activities for the quarter ending March 31, 2021.

**Highlights:**

- **Accelerated high priority EMD-003 Drug development program** via agreement with Cann Group
- **Developed evidence-generating care models** for **psychedelic-assisted therapy**
- **Continued recruitment** for **EMD-004** targeting irritable bowel syndrome
- **Added world-class experts to advisory** with appointment of:
  - *Dr. Karen Smith*, US biopharma executive, ex-CMO Jazz Pharmaceuticals
  - *Dr. Richard Mategaard*, ex-Naval officer and Consultant Psychiatrist
- **Expanded clinics** with new Emerald Clinics in Victoria and Western Australia
- **Awarded** part of **$880k grant** for **remote monitoring technology**

**Emyria's Managing Director, Dr. Michael Winlo,** said: "*Emyria has started 2021 with great momentum. We have secured access to a unique CBD dose product via a partnership with Cann Group. Combined with our real world data and drug development expertise, Emyria is well positioned to commence our pivotal clinical trials, the important first steps towards successful registration of an over-the-counter CBD product with the TGA.*

*We have also boosted our advisory teams with the addition of Dr. Karen Smith and Dr. Richard Magtengaard.*

*Dr. Smith has overseen many successful Drug registration programs with the FDA and was recently Chief Medical Officer at Jazz Pharmaceuticals, notable for recently acquiring GW Pharma, a cannabinoid medicine company, for $US7.2B.*

*Dr. Magtengaard is a retired Naval officer and consultant psychiatrist with a passion for treating the mental health of veterans and first responders.*

*During the quarter, Emyria added two new clinical sites to support our pivotal trial programs and our plans to launch evidence-generating psychedelic-assisted therapy.*

*Emyria's core remote monitoring technology was also recognised this quarter with a major grant award from the Western Australian Department of Health in partnership with collaborators at the University of Western Australia.*

*Finally, Emyria's revenue figures for the quarter reflect the milestone nature of data deal payments but also our increased focus and investment into developing our primary strategic assets - those are our proprietary data and drug registration programs."*

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Emyria Treatments

## EMD-003 - a unique cannabinoid dose form targeting psychological distress

Emyria and **Cann Group Limited (ASX: CAN)** will seek accelerated registration of a unique, low-dose, CBD-only capsule with Australia's Therapeutic Goods Administration (TGA). Successful registration as a Schedule 3 medicine would result in an **over-the-counter, pharmacist-only CBD medicine.**

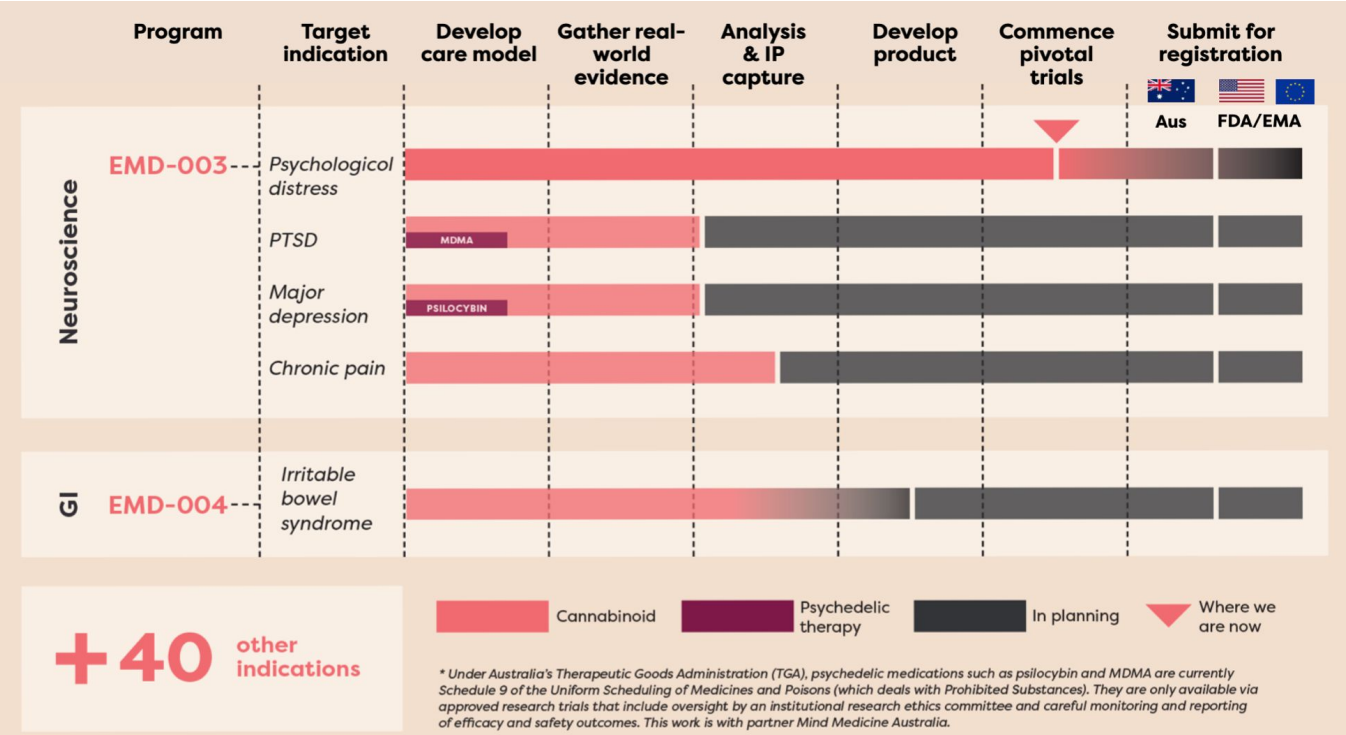
Emyria will lead the **EMD-003** drug development program using Cann Group's proprietary **Gelpell microsphere technology** to register a unique capsule form.

The collaboration capitalises on a number of **registration milestones** already met:

- **Real-world clinical data collected** on >**170 patients** already taking the dose form
- **Pivotal trial protocols developed** for target indication
- **Phase 1 trials already completed** for 10mg and 100mg doses of the capsule
- **Gelpell** has been shown to have **3.5 times the bioavailability** of oils (at 100mg)[1]

*[For further details, please see ASX announcements 29 MAR 21 and 30 MAR 30]*

## Emyria's pipeline targeting large, under-served patient populations




## FDA sees RWE role to guide CBD regulation, 75% of FDA applications use RWE [2]

Emyria welcomed an article from FDA leadership titled Better Data for a Better Understanding of the Use and Safety Profile of Cannabidiol (CBD) Products. Dr. Stephen Hahn[3], immediate past Commissioner of Food and Drugs and Dr. Amy Abernethy [4], Principal Deputy Commissioner stated: *"We think that real-world data (RWD) on CBD use and safety has a crucial role alongside data from other types of studies to fill in the current gaps in our understanding."* [5]

Emyria's real-world data contains of 2.6M data points covering more than 3,500 patients supporting registration programs for FDA and TGA.

*[See ASX announcement 27 JAN 2021]*

## Expanding Strategic Advisory

### Dr. Karen Smith



**Global pharmaceutical expert**, Dr. Karen Smith to Chair Emyria's Strategic Advisory Board.

Previously, Dr. Smith served as Executive Vice President, Global Head R&D and Chief Medical Officer of **Jazz Pharmaceuticals**, Inc., which recently acquired GW Pharmaceuticals for $7.2B USD.

Dr. Smith has overseen **more than 100 clinical trials** and more than **20 regulatory approvals** leading to product launches.

Dr. Smith's successful record includes **R&D and pipeline development**, **acquisition of U.S. and international companies**, divestitures and **negotiating partnership deals between biotech and pharma.**

Dr. Smith was founding Chief Executive Officer of **Minderoo Foundation's** Eliminate Cancer Initiative supported by Andrew Forrest and remains an advisor to that program.

*[See ASX announcement 22 FEB 2021]*

### Dr. Richard Magtengaard



**Consultant Psychiatrist** Dr. Richard Magtengaard, to join Emyria's Medical Advisory Board and support Emyria's multiple **mental health focussed initiatives.**

Dr. Magtengaard is a Consultant Psychiatrist with nearly 20 years of clinical and administrative experience and also served for 10 years as a **Commissioned Officer within the Royal Australian Navy**, before retiring to complete his Medical Degree.

Dr. Magtengaard is currently the **Director of the Military Trauma Recovery Programme** across 2 busy sites of care dedicated to assisting Defence Personnel, Veterans and other First Responder Organisations and their families, who have sustained physical and psychological traumas during the performance of their duties.

Richard is also Chair of the Medical Advisory Committee at Marian Centre Hospital, a member of St John Ambulance Expert Advisory Group and actively involved with:

- Australasian Military Medical Association (AMMA)
- ADF Joint Health Command (JHC)
- Returned Services League WA (RSLWA)
- St John Ambulance (SJA)
- West Australian Police (WAPOL)
- Department of Fire and Emergency Services (DFES)
- Australian Federal Police (AFP) and numerous other Ex-Service Organisations

*[See ASX announcement 01 FEB 2021]*

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Emyria Care

emerald clinics

## Clinic expansions

Emyria added Emerald Clinics sites in Victoria and Western Australia:

### East Melbourne

- New premises co-located with **Victorian Counseling and Psychological Services (VCPS)**, boosting Emyria's access to mental health services
- Further expansion opportunities in planning to support delivery of evidence-generating **psychedelic-assisted therapy** trials
- To increase patient access to Emerald Clinics and support pivotal registration trials planned for **EMD-003** targeting unmet needs in mental health



*[See ASX announcement 09 FEB 2021]*

### Perth

- Potential to double capacity in Perth
- Co-located with **West Leederville Private Hospital**
- Additional clinical rooms will also help support the pivotal clinical trials, currently in planning, in support of the registration of **EMD-003** and delivery of the grant from the WA Government



*[See ASX announcement 02 MAR 2021]*

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Emyria Digital Health

Openly

## Openly - successful Grant

Emyria's **remote monitoring digital health platform** and service - **Openly** - was **awarded a grant** from WA's Future Health Research and Innovation Fund.

The successful grant titled *"An advanced digital monitoring and engagement platform for at-risk and confirmed COVID-19 individuals"* is intended to boost Western Australia's digital health infrastructure and capacity to manage health challenges like COVID-19.

The aims of the grant are to evaluate the utility of **advanced digital health monitoring in vulnerable patient populations**, to improve engagement amongst aged and ethnic populations and to **improve mental health** evaluation and monitoring for those under remote care.

Emyria will take a leadership role in the grant and will lead a multidisciplinary collaboration involving the state's major health services and universities. The grant will also extend Emyria's collaboration with Mt Sinai, New York.

*[See ASX announcement 05 FEB 2021]*

## CORPORATE

### Cash
Emyria has $3.5M cash as of March 31, 2021.

Subsequent to the end of this quarter, on 21 April 21, Emyria completed a capital raising of $5M to accelerate the Company's planned clinical studies and business expansions.

The board of directors were paid $269,000 for the quarter ended 31 March 2021 (as disclosed in section 6 of the 4C quarterly report) and this comprised wages, fees and superannuation.

### Outlook
Emyria will continue its focus on initiating and completing pivotal clinical trials for the **EMD-003 program** seeking to register a cannabinoid-based medicine with a unique capsule dose form to reduce symptoms of anxiety, depression and stress.

Emyria is also advancing the EMD-004 program - targeting irritable bowel syndrome and scoping pipeline expansion **therapeutically** (with **psychedelic-assisted therap**y) and **geographically** (FDA pathways). The company will provide further updates to the market accordingly.

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## PROMOTIONS DURING QUARTER

### Mind Medicine Australia Webinar
https://www.youtube.com/watch?v=P-_pW94HniQ

### Pitt Street Research Cannabis & Hemp Conference
https://stocksdownunder.com/video/stocks-down-under-cannabis-hemp-investor-conference/
No not for a quarterly.

### Broker Briefing 'Technology of Tomorrow' Webinar
https://emyria.com/2021/03/16/presentation-Dr.-michael-winlo-on-broker-briefing/

### Webinar on Partnership with Cann Group Limited
https://youtu.be/7BvZwkFcPRo

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## REFERENCES

[1] Atsmon J, Heffetz D, Deutsch L, Deutsch F, Sacks H. Single-Dose Pharmacokinetics of Oral Cannabidiol Following Administration of PTL101: A New Formulation Based on Gelatin Matrix Pellets Technology. Clin Pharmacol Drug Dev. 2018 Sep;7(7):751-758. doi: 10.1002/cpdd.408. Epub 2017 Nov 10. PMID: 29125702.
[2] The role of real-world evidence in FDA approvals (eBook) - https://aetion.com Accessed 26 Jan 21
[3]Prior to the FDA, Dr Stephen Hahn was a practicing clinician / scientist at the Texas Medical Centre
[4]Prior to the FDA, Dr Amy Abernethy was Chief Medical Officer at Flatiron Health, a RWE company that was acquired by Roche for $1.9B USD in 2018
[5]https://www.fda.gov/news-events/fda-voices/better-data-better-understanding-use-and-safety-profile-cannabidiol-cbd-products

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## USE OF FUNDS AS AT 31 MARCH 2020

| | Use of Funds reported in Prospectus on 11 Dec 19 | Expenditure period 11 Dec 19 to 31 Mar 21 |
|---|---|---|
| | **$'000s** | **$'000s** |
| Clinic Operations - Existing | 2,500 | 1,378 |
| Develop Data Platform* | 800 | 1,534 |
| Clinical Trials | 800 | - |
| Clinics Development - New and Existing | 800 | - |
| Corporate Overheads | 1,600 | 2,710 |
| Business Development | - | 284 |
| Cost of the Offers | 682 | 931 |
| Working Capital | 518 | 590 |
| | | |
| **Total Expenditure** | **7,700** | **7,427** |

Please note that the "Use of Funds" for the 12-month period post admission, disclosed above, was prepared prior to the international spread of COVID-19. This significant external event, which is continuing to affect the operations of many companies and other organisations with which the Company engages, may potentially impact on future allocation of expenditure for the Company. At this point in time, the pandemic's human health and economic impacts are unknown. Ongoing national and international travel restrictions and lockdowns, quarantine and social distancing measures and other interventions undertaken in response to COVID-19 may impact on the Company's operations and allocation of funds in the future. In light of this, the Company will continuously monitor its capital investment opportunities and review its operations and update the market accordingly.

This announcement has been approved and authorised for release by the Board of Emyria Limited.

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## About Emyria (www.emyria.com)

Emyria Limited is a data-backed, drug development company. **Emyria's Treatments** target unmet needs and are focused on obtaining approval from major global regulators. Emyria's drug development programs are informed by insights generated from extensive analysis of **Emyria Data** - deep, ethically-sourced clinical evidence that is gathered with patients across Emyria's independent clinical services (**Emerald Clinics** - www.emeraldclinics.com.au)

**Emyria Data** provides deep treatment insights and is therefore a source of unique IP, strategically designed drug development and personalised care programs.

### Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, the company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to successfully develop its product candidates and timely complete its planned clinical programs and the Company's ability to obtain marketing approvals for its product candidates. In addition, the forward-looking statements included in this press release represents the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

# Appendix 4C

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

| **Name of entity** | |
|---|---|
| EMRYIA LIMITED | |
| **ABN** | **Quarter ended ("current quarter")** |
| 96 625 085 734 | 31 March 2021 |

| **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 | 380 | 1,530 |
| 1.2 | Payments for | | |
| | (a) research and development (includes allocated salaries) | (734) | (2,347) |
| | (b) clinic operating costs (includes allocated salaries) | (383) | (1,536) |
| | (c) advertising and marketing | (120) | (325) |
| | (d) leased assets | (44) | (110) |
| | (e) staff costs (unallocated salaries) | (206) | (700) |
| | (f) administration and corporate costs | (184) | (501) |
| 1.3 | Dividends received (see note 3) | - | - |
| 1.4 | Interest received | 5 | 19 |
| 1.5 | Interest and other costs of finance paid | (2) | (13) |
| 1.6 | Income taxes paid | - | - |
| 1.7 | Government grants and tax incentives | - | 954 |
| 1.8 | Other (provide details if material) | - | - |
| **1.9** | **Net cash from / (used in) operating activities** | **(1,288)** | **(3,029)** |

| | | | |
|---|---|---|---|
| **2.** | **Cash flows from investing activities** | | |
| 2.1 | Payments to acquire: | | |
| | (a) entities | - | - |
| | (b) businesses | - | - |
| | (c) property, plant and equipment | (8) | (51) |
| | (d) investments | - | - |
| | (e) intellectual property | - | - |

| Consolidated statement of cash flows | | Current quarter $A'000 | Year to date (9 months) $A'000 |
|---|---|---|---|
| | (f) other non-current assets | - | - |
| 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 (provide details if material) | - | - |
| **2.6** | **Net cash from / (used in) investing activities** | **(8)** | **(51)** |

| | | | |
|---|---|---|---|
| **3.** | **Cash flows from financing activities** | | |
| 3.1 | Proceeds from issues of equity securities (excluding convertible debt securities) | - | 3,400 |
| 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 | - | (205) |
| 3.5 | Proceeds from borrowings | - | - |
| 3.6 | Repayment of borrowings | - | (259) |
| 3.7 | Transaction costs related to loans and borrowings | - | - |
| 3.8 | Dividends paid | - | - |
| 3.9 | Other – net payments from cash backed guarantees | (37) | 6 |
| **3.10** | **Net cash from / (used in) financing activities** | **(37)** | **2,942** |

| | | | |
|---|---|---|---|
| **4.** | **Net increase / (decrease) in cash and cash equivalents for the period** | | |
| 4.1 | Cash and cash equivalents at beginning of period | 4,869 | 3,686 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (1,288) | (3,029) |

| Consolidated statement of cash flows | | Current quarter $A'000 | Year to date (9 months) $A'000 |
|---|---|---|---|
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above) | (8) | (51) |
| 4.4 | Net cash from / (used in) financing activities (item 3.10 above) | (37) | 2,942 |
| 4.5 | Effect of movement in exchange rates on cash held | 4 | (8) |
| **4.6** | **Cash and cash equivalents at end of period** | **3,540** | **3,540** |

| 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 | 3,540 | 4,869 |
| 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)** | **3,540** | **4,869** |

| 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 | 269 |
| 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**<br>*Note: the term "facility' includes all forms of financing arrangements available to the entity.*<br>*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) | (1,288) |
| 8.2 | Cash and cash equivalents at quarter end (Item 4.6) | 3,540 |
| 8.3 | Unused finance facilities available at quarter end (Item 7.5) | - |
| 8.4 | Total available funding (Item 8.2 + Item 8.3) | 3,540 |
| 8.5 | **Estimated quarters of funding available (Item 8.4 divided by Item 8.1)** | 2.7 |

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

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

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

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

## 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: .....

Authorised by: Simon Robertson .....
(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.