

## Q2 FY23 QUARTERLY ACTIVITIES REPORT & APPENDIX 4C

### Strategic partnership with global diagnostic leader Sonic Healthcare

#### Key Highlights

30 Jan 2023

- **Sonic Healthcare acquired a 19.9% stake in Microba and entered into a global commercial partnership spanning 7 major regions**
  - Sonic Healthcare (ASX: SHL) invested \$17.8m to acquire a 19.99% equity holding in Microba at \$0.26 per share and sought to acquire options for a further 5% stake subject to shareholder approval at an EGM to be held on 1 February 2023 – providing Sonic with a strategic shareholding in Microba.
  - Microba and Sonic have agreed initial terms for a strategic partnership to deliver Microba's microbiome testing technology into Australia, Germany, United Kingdom, Switzerland, US, NZ and Belgium. The full license and distribution arrangements are expected to be finalised over the coming months.
  - Sonic Healthcare is one of the world's largest medical diagnostics companies which globally employs more than 41,000 people and generated revenue of \$9.3 billion in FY22.
  - The partnership is expected to increase Microba's addressable market through distribution of Microba's testing throughout Sonic's global network of primary and specialist healthcare professionals.
- **Distribution expansion with Europe's largest pathology company**
  - In October, Microba and SYNLAB executed a major amendment to a master agreement between the companies to enable distribution expansion across Europe and Latin America
  - Aligned to the amendment, new agreements have been executed, operations commenced, and first sales achieved with SYNLAB affiliate organisations across Italy and Portugal
  - Italy is the third largest probiotic market in the world (by sales), highlighting the awareness of gut health and making it a key market for microbiome testing.
- **Therapeutic program advancement**
  - An important catalyst in the sector was completed – on 30 November 2022 Ferring Pharmaceuticals (Rebiotix) achieved the first ever microbiome drug approval with the FDA, paving the way for Microba's novel therapeutics currently in development.
  - Inflammatory Bowel Disease program – Clinical GMP manufacturing progressing to schedule and positive formal feedback received from the FDA. Program remains on track for upcoming Phase I clinical trial scheduled for Q4 FY23.
  - Immuno-oncology program – pre-clinical animal models progressed on schedule. First results expected February - March 2023.
  - Autoimmune disease program – program on track and robust dataset being generated with Ginkgo Bioworks (NYSE: DNA). First data expected throughout January - March 2023.

- **Financial performance**
  - Q2 FY23 cash receipts totalling 1.61m representing 43% growth on the prior comparative period, Q2 FY22.
  - Q2 FY23 unaudited revenue totalled \$1.2m, which is on track with our internal budget, and tracking towards positive growth for FY23.
  - \$2.62m R&D Tax Incentive received for Research & Development Activities conducted during FY22.
- **\$41.95 million in cash or equivalents as at 31 December 2022 – the Sonic Healthcare strategic investment provided further strength to Microba’s balance sheet during a time of volatility and uncertainty across the global macroeconomic environment, and these funds enable Microba to:**
  - Invest with confidence to accelerate our therapeutic programs over the coming years towards major milestones and big pharma transactions; and
  - Further support the international expansion and scaling of the Company’s testing services.
- **The Company will host an investor webinar with CEO Dr Luke Reid at 10:30am AEDT (Sydney/Melbourne) / 9:30am AEST (Brisbane) on Tuesday, 31 January 2023. [Register here for the webinar](#)**

**Microba Life Sciences Limited** (ASX: MAP) (“Microba” or the “Company”), a precision microbiome Company, is pleased to provide a summary of its activities for the quarter ended 31 December 2022.

**CEO Dr Luke Reid said:**

*“We are continuing to deliver on our FY23 goals towards another year of positive growth. For Microba’s testing services, our new strategic partnership with global medical diagnostics leader Sonic Healthcare further supports global distribution expansion for our testing services, and bolsters our balance sheet enabling the Company to continue executing with confidence. Sonic, SYNLAB, Genova Diagnostics and G42 Healthcare give us access into major healthcare markets across the globe and position Microba for growth over the coming years.*

*For Microba’s therapeutics, a major catalyst for the sector occurred with the first FDA approval of a live microbiome drug received by Ferring Pharmaceuticals. A second approval is expected next quarter for Seres Therapeutics. These approvals demonstrate a clear path to market for microbiome drugs, an important catalyst for further investment into the sector. With Microba’s progress into the clinic with MAP 315 and Microba’s growing intellectual property portfolio we are in a strong position to advance the Company’s pipeline towards out-licensing deals”*

**First FDA approval – the start of a therapeutic revolution**

A major milestone occurred in the microbiome therapeutics sector during the quarter. Live microbial cell therapies, also known as “Live Biotherapeutic Products” (LBPs) are an entirely new class of drug. These drugs represent an attractive new treatment option for patients with potential novel therapeutic activities and strong safety profiles, however prior to November 2022, no U.S. Food and Drug Administration (FDA) LBPs had been approved. A clear regulatory path to market is critical for drug developers and pharma companies to invest with confidence to bring these drugs to patients. On 30 November 2022 Ferring-Rebiotix received full FDA approval of their First Generation<sup>1</sup>, donor derived, enema delivered LBP for the treatment of recurrent C. difficile infection (rCDI). This approval represents an important catalyst for the sector and supports a path to market for Microba’s Next Generation<sup>2</sup> microbiome drugs. Next quarter, the second FDA approval is

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<sup>1</sup> Human fecal donor derived drug products which are reliant on ongoing donor material supply to manufacture

<sup>2</sup> Single strain LBP or microbiome derived small molecule drugs amenable to scalable cGMP manufacturing

expected to be granted to Seres Therapeutics Inc. (NASDAQ: MCRB) first generation, donor derived, oral LBP for the treatment of rCDI. Seres has been granted an FDA priority review action date<sup>3</sup> and is expecting approval on 26 April 2023. These approvals are well timed as Microba transitions into the clinic with Microba's Next Generation<sup>4</sup> microbiome drug MAP 315 for the treatment of Inflammatory Bowel Disease.

### **Major new partnership with Sonic Healthcare**

Sonic Healthcare (ASX: SHL) is a globally trusted leader in medical diagnostics. Sonic is the second largest healthcare Company in Australia, which globally employs more than 41,000 people and generated revenue of \$9.3 billion in FY22. In November 2022 Microba entered into a strategic partnership with Sonic which deeply aligned the interests of both companies to bring microbiome testing and therapeutics into the hands of clinicians and patients globally to improve standard of care. Firstly, Sonic invested \$17.8m to acquire a 19.99% shareholding in Microba. In addition, Sonic is seeking to acquire options for an additional 5% equity position, subject to shareholder approval at an upcoming EGM to be held on 1 February 2023. Further, Microba and Sonic entered into initial terms of an agreement which enables Sonic and its subsidiaries to distribute Microba's microbiome testing products to its customers, including general practitioners and specialists, across Australia, New Zealand, Germany, United Kingdom, Belgium, Switzerland and the United States. This major global partnership with one of the world's leading providers of medical diagnostics delivers another significant expansion in global distribution for Microba's leading microbiome testing technology. The partnership is expected to significantly increase Microba's addressable market by bringing Microba's testing products to Sonic Healthcare's primary and specialist healthcare professional customer base. The full license and distribution arrangements are expected to be finalised over the coming months.

### **Expanding across Europe with SYNLAB**

SYNLAB (FRA: SYAB) is the largest European clinical laboratory and medical diagnostic services Company by revenue and number of tests, servicing around 100 million patients annually. In 2020, Microba entered into a master agreement with SYNLAB International GmbH and an agreement with SYNLAB Diagnosticos Globales to deliver Microba's testing solution to Healthcare Providers in Spain, with an option to formalise distribution agreements with their affiliate organisations across 36 countries. With positive sales results in Spain, in October 2022 SYNLAB further activated their rights to pursue formal expansion into additional countries across Europe and Latin America through a major amendment to the master agreement. Aligned to this, during the quarter a first group of new agreements were signed with SYNLAB affiliate organisations Synlab Italia Srl and SYNLABHEALTH II S.A. for Italy and Portugal respectively. These countries have already been operationalised with their Microba powered test, and first sales achieved. Italy is a particularly important market given the demand for gut health solutions, which is exemplified through it being the third largest market in the world for probiotic sales. Expansion into both Italy and Portugal, two important European markets, is another positive advancement in distribution with SYNLAB. This further exemplifies SYNLAB's conviction and commitment to the Microba testing technology.

### **Testing services growth with access into 35 countries and 7 now operationalised**

Sonic Healthcare is a significant addition to Microba's bench of leading medical diagnostic and healthcare partners. Together, Sonic Healthcare, SYNLAB, Genova Diagnostics and G42 Healthcare provide us with strong access into major global healthcare markets across the globe:

- Sonic Healthcare > UK, Germany, Switzerland, Belgium, Australia, NZ & US
- SYNLAB > Broader Europe & LATAM
- Genova Diagnostics > US
- G42 Healthcare > Middle East (GCC Region)

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<sup>3</sup> Priority Review designation with a Prescription Drug User Fee Act (PDUFA)

<sup>4</sup> Single strain LBP or microbiome derived small molecule drugs amenable to scalable cGMP manufacturing

Through this network, we have access into 35 countries, and to date we have now activated operations into 7 of those countries including the recent additions of Italy and Portugal in the quarter. This provides solid foundations for growth as we progressively operationalise and activate these countries to provide Microba-powered testing to clinicians and their patients. By the end of the financial year we expect to have doubled the size of the country base from 4 in FY22 to 8 by the end of FY23. We anticipate an impact on revenue from the new partnership with Sonic Healthcare in FY24.

### **New healthcare product launch positioned for February**

A core component of Microba's strategy is to advance the clinical utility of microbiome testing to become embedded as a routine part of health and disease management. Aligned to this, Microba has been developing a next generation product suite for health professionals that was scheduled for a full feature launch in Nov 2022. The new product suite leverages Microba's ISO15189 standard laboratory and diagnostic testing solutions to enable health professionals to comprehensively assess gut microbiome biomarkers and other gastrointestinal markers for their patients, and identify opportunities to intervene through diet, lifestyle and supplementation. In addition, the product suite enables diagnostic testing for gastrointestinal pathogens. These products are breaking new ground at the forefront of the clinical utility of comprehensive microbiome testing, and more generally in the use of next generation DNA sequencing technologies applied in this setting. Through engagement with the TGA during the quarter, a different regulatory classification for a component of the new product suite was defined which requires additional time to document and finalise. Launch of the product suite is now scheduled for Feb 2023. These new products will be initially launched in Australia and then rolled out through Microba's growing international distribution networks. The products significantly advance the clinical utility of microbiome testing in a healthcare setting, and are expected to expand the total addressable market for Microba's testing products.

### **IBD Program - MAP315 progressing towards Phase I**

Microba is progressing its novel microbial cell therapy lead candidate, MAP 315, into its first in human Phase I clinical trial. Over the quarter, manufacturing of MAP 315 further progressed with Bacthera in Switzerland with engineering production through to full encapsulated drug product. Clinical GMP manufacturing is on track for Q3 2023. Positive formal feedback has been received from the FDA on our Pre-IND briefing book and pre-clinical package. This supports our upcoming HREC submission for Phase 1 study initiation, scheduled for Q4 FY23, and provides a roadmap toward a global Phase II study for MAP 315. MAP 315 is being developed for the treatment of Ulcerative Colitis, a debilitating form of Inflammatory Bowel Disease with >50% of patients unable to achieve sustained remission. The global market for Ulcerative Colitis treatments was valued at \$7.5B in 2021.

### **Immuno-Oncology Program – Driving towards pre-clinical efficacy data**

Pre-clinical animal model experiments with Eurofins on Microba's 3 Immuno-Oncology leads are progressing well with first results expected February - March 2023. This work will provide important pre-clinical efficacy data on the potential of these novel microbial cell therapy leads to increase response to immune checkpoint inhibitor (ICI) therapy. Microba's Immuno-Oncology program is targeting the development of a therapeutic to improve response rates in cancer patients receiving immune checkpoint inhibitor (ICI) therapy. Global immune checkpoint inhibitor sales have grown substantially since Microba has commenced the program, with Merck announcing sales of the market leading drug Keytruda of \$5.4bn USD in Q3 2022<sup>5</sup>.

### **Autoimmune Disease Program – tracking towards first data**

Bacterial strains supplied from the Company's biobank are continuing to progress through characterisation and screening with strategic shareholder and partner Ginkgo Bioworks (NYSE: DNA) at their laboratories in Boston, US. Core technical competencies have been established with Ginkgo which enable progression into the next stage of broad bioassay testing. We have been pleased with the early data readouts showing reproducibility with first in vitro screening data expected to be

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<sup>5</sup> <https://www.merck.com/news/merck-announces-third-quarter-2022-financial-results/#:~:text=Pharmaceutical%20revenue&text=Growth%20in%20oncology%20was%20largely,%245.4%20billion%20in%20the%20quarter.>

available throughout January to March 2023 as part of the 2-year discovery program which kicked off in mid-2022. Microba's Autoimmune Disease program is targeting three autoimmune disorders lupus, psoriatic arthritis and autoimmune liver diseases. The global market for autoimmune disease treatments was estimated to be US\$53.2 billion in 2019 and forecast to grow to US\$90.7 billion by 2024<sup>6</sup>.

### Financial Update

Unaudited revenue for the December 2022 quarter totalled \$1.2m. Cash receipts for the December 2022 quarter totalled \$1.61m representing 43% growth on the prior corresponding period, Q2 FY22. These financial results are aligned to internal budgets and are tracking towards another year of positive growth for the Company. As messaged previously, the financial year's growth is expected to be weighted to the second half of the financial year aligned to timing of sales ramp up of new distribution partners, launch of new healthcare product, seasonality of service demand, and aligned revenue recognition.

Net cash inflows during the quarter amounted to \$15.49 million and includes a \$17.8m investment from Sonic Healthcare.

As at 31 December 2022, Microba had \$41.95 million in cash or equivalents. This puts the Company in a very strong position to execute its growth strategy and provides a robust runway to support the advancement of the Company's therapeutic programs during ongoing economic volatility.

In accordance with Listing Rule 4.7C, payments made during the quarter to related parties and their associates included in item 6.1 of the Appendix 4C was \$120,000 and included Director fees.

### Use of Funds

In section 7.4 of the Microba Life Sciences Prospectus, the Company provided a proposed use of funds statement for 24 months from listing. The table below only shows use of funds from IPO to the end of the most recent quarter, 31 December 2022. The Companies funding has been strengthened as a result of the \$17.8m investment made by Sonic Healthcare, this has been subsequently added to the use of funds table.

Use of Funds	Dec-22 Qtr	Prior Total	Total Expenditure	Prospectus
Global market penetration and sales growth	680	1,490	2,169	7,200
Data driven drug discovery	596	4,233	3,638	13,100
Platform technology advancement	975	890	1,866	2,500
Administrative and working capital	546	2,227	2,773	4,700
Costs of the offer	-	2,429	2,429	2,500
Further capital raised – Sonic Healthcare	17,237	-	-	-
<b>Total</b>	<b>15,632</b>	<b>11,270</b>	<b>12,875</b>	<b>30,000</b>

During the three-month period ended December 2022, overall expenditure remained in line with the estimated use of funds as set out in the Prospectus.

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*This announcement has been authorised for release by the Board.*

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<sup>6</sup> BCC Research. Autoimmune Disorder Therapies: Global Markets (2020).

For further information, please contact:

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**About Microba Life Sciences Limited**

Microba Life Sciences is a precision microbiome company driven to improve human health. With world-leading technology for measuring the human gut microbiome, Microba is driving the discovery and development of novel therapeutics for major chronic diseases and delivering gut microbiome testing services globally to researchers, clinicians, and consumers. Through partnerships with leading organisations, Microba is powering the discovery of new relationships between the microbiome, health and disease for the development of new health solutions.

**For more information visit: [www.microba.com](http://www.microba.com)**

Microba encourages all current investors to go paperless by registering their details with the designated registry service provider, Automic Group, whose contact information is housed on the Investor Relations page of the Company's website.

## Appendix 4C

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

**Name of entity**

Microba Life Sciences Limited, and controlled entities

**ABN**

82 617 096 652

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

31 December 2022

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (6 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	1,609	3,407
1.2 Payments for		
(a) research and development	(1,825)	(3,470)
(b) product manufacturing and operating costs	(574)	(1,391)
(c) advertising and marketing	(383)	(602)
(d) leased assets	(141)	(291)
(e) staff costs	(1,574)	(3,446)
(f) administration and corporate costs	(748)	(1,490)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	132	146
1.5 Interest and other costs of finance paid	(4)	(8)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	2,668	2,686
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(840)</b>	<b>(4,459)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(30)	(142)
(d) investments	-	-
(e) intellectual property	(623)	(1,273)
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>(653)</b>	<b>(1,415)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	17,833	17,833
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	(596)	(596)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(112)	(224)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>17,125</b>	<b>17,013</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	26,462	30,581
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(840)	(4,459)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(653)	(1,415)

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (6 months) \$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	17,125	17,013
4.5	Effect of movement in exchange rates on cash held	(141)	233
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>41,953</b>	<b>41,953</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	39,749	22,988
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other - Restricted Cash* (current)	2,204	3,474
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>41,953</b>	<b>26,462</b>

\*Relates to cash held in a Microba escrow account for the purposes of satisfying Ginkgo Bioworks R&D activities during FY23.

<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	(120)
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.*

## 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.</i>		
<i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	(112)	(112)
<b>7.4 Total financing facilities</b>	<b>(112)</b>	<b>(112)</b>
<b>7.5 Unused financing facilities available at quarter end</b>		<b>0</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.		
An unsecured insurance premium funding arrangement was entered into to finance the Group's annual insurance premiums. The balance originally drawn was \$425k, the balance drawn at quarter end was \$112k, and is repayable over 11 equal monthly instalments, with a fixed interest rate of 3.093%.		

<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)	(840)
8.2 Cash and cash equivalents at quarter end (item 4.6)	41,953
8.3 Unused finance facilities available at quarter end (item 7.5)	0
8.4 Total available funding (item 8.2 + item 8.3)	41,953
<b>8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>49.9</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?	
Answer: N/A	
8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?	
Answer: N/A	
8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?	
Answer: N/A	
<i>Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.</i>	

## Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 30 January 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.