ASX Announcement | 29 April 2024
AdAlta Limited (ASX:1AD)

QUARTERLY ACTIVITIES REPORT – MARCH QUARTER 2024

Significant AD-214 Phase I extension study results, progress on strategic priorities and financing

Key highlights

- AD-214 Phase I extension study achieved critical milestone for Phase II, accelerating partnering efforts
- Memorandum of Understanding executed with SYNthesis BioVentures to investigate development of next generation cellular immunotherapies for solid cancers (post period end)
- Up to $3.7 million flexible institutional investment facility secured to pursue additional strategic initiatives (post period end)
- Victorian Government RDTI Advance Loan Facility extended until October 2024 (post period end)

AdAlta Limited (ASX:1AD) ("AdAlta" or "the Company") is pleased to announce its March quarter 2024 results. The quarter featured completion of the Phase I extension study of AD-214 with the results establishing the safety, tolerability, availability and activity of the intended Phase II dose, a critical milestone to advancing the partnering discussions to finance Phase II. Post period end the Company announced a Memorandum of Understanding ("MoU") with SYNthesis BioVentures ("SYNBV") to investigate forming a jointly owned special purpose entity to bring Asian cellular immunotherapies to western regulated markets and provide access AdAlta's i-body® technology. The Company reported a cash balance of $1.51 million at 31 March ($3.68 million at 31 December 2023) and post period end announced a new flexible institutional investment of up to $3.7 million and extension of the Victorian Government RDTI Advance Loan Facility until October 2024.

Reflecting on the quarter, AdAlta's CEO and Managing Director, Dr Tim Oldham commented:

"Our Phase I extension study of AD-214 achieved a critical milestone during the quarter, successfully establishing the projected safety, activity and availability of the molecule at the intended Phase II clinical dose and addressing key partnering questions. This has enabled us to accelerate and advance licensing and fully funded co-development collaborations discussions to secure funding for Phase II. We continue to be encouraged by the progress of these discussions.

"We were also pleased to be able to refine and progress our strategy to secure near to clinic assets that complement the i-body technology and support growth beyond AD-214, focussing on provide innovative cellular immunotherapies originating in Asia with a pathway to western regulated markets via Australian clinical trials and further enhancement with AdAlta's i-body® technology. This culminated in our Memorandum of Understanding with SYNthesis BioVentures that will strengthen our capabilities and increase the pace at which we can execute this exciting strategy.

"Our new institutional investment with New Life Sciences Capital and existing shareholder, the Meurs Group enables us to look beyond potential AD-214 transactions and advance our SYNthesis BioVentures collaboration and our i-body® programs with greater financing certainty. The flexible nature of this investment means we only draw down what we need and can continue to maximise any non-dilutive financing that may come from an AD-214 transaction."

A. Operations overview

1. Realising the value of lead asset AD-214

Priority: generate a return on investment by securing non-dilutive financing of Phase II clinical studies that realises value created by AdAlta

AdAlta's lead product, AD-214, is a first in class, next generation antibody therapeutic for the treatment of fibrotic diseases including lung fibrosis (specifically Idiopathic Pulmonary Fibrosis (IPF) and Interstitial Lung Disease (ILD)), kidney fibrosis, eye fibrosis and some cancers. The Company's priority is to finance progression of AD-214 into Phase II clinical studies in IPF or kidney fibrosis through partnerships.

Final data from Phase I extension study supports safety profile and Phase II dose selection, de-risking Phase II studies

As previously announced (August 2023), AdAlta commenced a Phase I extension clinical study of AD-214 in healthy volunteers to establish the safety of multiple 10 mg/kg doses of AD-214 and confirm this as the target dosing regimen for Phase II clinical efficacy studies. The study was completed during the March 2024 quarter.

The key findings of the study were:

- AD-214 was well tolerated at 10 mg/kg intravenously (IV) every two weeks.
- The bioavailability and pharmacokinetics (PK) of AD-214 was consistent across all doses and with prior single dose studies.
- The pharmacodynamic (PD) activity of AD-214 as measured by transient changes in white blood cell counts was consistent across all doses and with prior single dose studies. Duration of receptor occupancy was consistent with prior studies and dosing simulations and supports dosing every two weeks.
- Antidrug antibodies (ADAs) were detected at low levels in all participants in the study but did not affect AD-214 PK or PD. This supports our hypothesis that the low levels of ADAs are unlikely to be of clinical safety or efficacy concern.

AdAlta's plan is to evaluate 10 mg/kg intravenous doses of AD-214 every two weeks as treatment for IPF. Completion of the Phase I extension study completes the safety and dose selection data package to support progressing this dose regimen into Phase II clinical studies.

Partnering discussions continues to progress satisfactorily, offering near term upside if successful

AdAlta is pursuing two parallel strategies to secure the necessary financing for Phase II clinical trials and to generate a return on its investment to date in AD-214:

1. Out-licensing of AD-214 to large biopharmaceutical companies who would then conduct Phase II and further studies.
2. Co-developing AD-214 in an asset specific investment vehicle managed by AdAlta and financed by third party strategic or financial investors.

AdAlta will provide updates on these partnering discussions when binding commitments are in place.

2. Progressing existing i-body enabled therapeutic programs

AdAlta's existing immuno-oncology co-development programs, with Carina Biotech (i-CAR-T) and GE Healthcare (i-PET imaging), continued to progress without achieving material milestones during the quarter.

AdAlta has identified the potential for the i-body® platform to become a key building block of advanced cell and gene therapy products, and particularly i-body® enabled Chimeric Antigen Receptor-T cell (i-CAR-T cell) therapies for solid tumours. AdAlta's i-CAR-T collaboration with Carina Biotech is now working on three potential products (all at early discovery stage with the most advanced in initial *in vivo* animal studies). Building on this collaboration, a clear opportunity is emerging to use the i-body® platform as the smallest available tool to help direct these transformational therapies specifically to cancer and/or to enhance their

function when they arrive. Future discovery programs focussing on i-bodies for application in cellular immunotherapy have been identified and the Company continues business development initiatives for sponsored research and co-development collaborations in this field and the related applications of gene and mRNA delivered therapies.

During the quarter, we continued work to refine the potential applications of the new i-body® discovered with La Trobe University (announced December 2023) that is believed to be the first ever antibody-like molecule capable of high potency inhibition of malaria parasite invasion of red blood cells and liver cells across multiple strains of the parasite. This will enable us to submit grant applications to progress this work.

3. Investing in our platform and pipeline

Post quarter end, AdAlta announced the execution of a Memorandum of Understanding (MoU) with SYNthesis BioVentures (SYNBV) to investigate the formation of a jointly owned entity, to be called AdCella, that, once established, will provide innovative cellular immunotherapies originating in Asia with a pathway to western regulated markets via Australian clinical trials and further enhancement with AdAlta's i-body® technology.

AdCella's objective, once formed, is to identify partners with technology platforms capable of developing multi-functional cellular immunotherapies addressing the challenges of trafficking, targeting and immune suppression in solid tumours. AdCella would then license or acquire global (outside Asia) commercialisation rights to these products in return for conducting initial clinical trials for western regulated markets in Australia and providing access to AdAlta's i-body® technology for integration into their future product pipeline. Many of the initial assets would be substantially de-risked because they will have already generated clinical data in their "home" markets.

AdCella is the next step in AdAlta's stated strategy of building out its product development business by securing clinical stage assets that complement the i-body® platform. SYNBV's deep expertise in cross border transactions and access to alternative capital sources, especially with China, is highly complementary to AdAlta's operational and technology skills and enables AdAlta to accelerate execution of its strategy.

With AdCella as their bridge to western regulated markets, partner companies will gain unique access to Australia's clinical and manufacturing ecosystem, AdAlta's capabilities to conduct clinical trials acceptable to US FDA, AdAlta's i-body® platform for the next generation of multi-functional cellular immunotherapy products in their pipeline and access to both public and private sources of capital. Australian patients may benefit from earlier access to these new therapies than would otherwise be possible without AdCella.

4. Near term milestones

AdAlta's milestones and data read-outs for the next six months include:

Goal	Status as at 31 Dec 2023	Status as at 31 Mar 2024
AD-214		
Final HV participant visit for AD-214 Phase I extension study	Achieved (Jan'24)	Achieved (Jan'24)
Full safety and tolerability results for AD-214 Phase I extension study	On track	Achieved (Mar'24)

Carina collaboration		
In vivo proof of concept results of A-i-CAR-T cells	H1'24	H2'24
Discovery programs for targets B and C continue	On track	Due to complete H2'24
i-body® platform and pipeline		
Commence discovery on two new "catalogue" targets for i-CAR-T	Commenced	Commenced
Complete establishment of AdCella under SYNBV MoU	-	Q4'24

AdAlta is not explicitly forecasting the timing or value of any future partnering or licensing deal for AD-214 or in-licensing deal for AdCella.

B. Corporate and organization updates – new institutional investment for up to $3.7 million

Concurrently with this report, AdAlta has announced two new institutional investments together amounting to up to $3.7 million by New Life Sciences Capital, LLC ("NLSC") and an entity associated with leading existing shareholder the Meurs Group (together "Investors"). The initial investment tranches amounting to $1.2 million are anticipated to be received over the next three weeks. The Company utilised its existing and available placement capacity under Listing Rule 7.1 to agree the initial investment. Subsequent investments, should the Company elect to draw them down, will be undertaken only if placement capacity under Listing Rule 7.1 is available.

Proceeds from the investment will be used to accelerate progress under the MoU with SYNBV and to progress internal i-body® programs independently of the availability of funding from ongoing partnering initiatives for lead asset AD-214.

This financing provides important strategic flexibility for AdAlta. Satisfactory progress is being made towards near term partnerships to finance Phase II clinical trials for AD-214, however other strategic initiatives could not be advanced rapidly without additional finance. Through this support from New Life Sciences Capital and major shareholder the Meurs Group, the Company is able to look beyond potential AD-214 transactions and advance these initiatives with greater financing certainty. The flexible nature of this investment means AdAlta need only draw down funds as needed and can continue to maximise any non-dilutive financing that may come from an AD-214 transaction or other sources.

The Company issued 10,000 Ordinary Shares during the period upon exercise of 1ADOA options.

C. Financial position – cash reserves secured with new financing and extension of RDTI Loan Facility

The Company is current finalising an extension of the Treasury Corporation of Victoria (TCV) loan facility (Facility) extended to AdAlta as part of the Victorian Government's R&D Cash Flow Loan Initiative.

The table below outlines the terms of the Facility as announced on 18 October 2023 and the amended terms as agreed by AdAlta Limited and Invest Victoria. The amendment is subject only to execution of the formal extension agreement by AdAlta Limited and TCV. Full repayment of the facility is expected to be upon receipt of AdAlta's Research and Development Tax Incentive (RDTI) rebate in respect of FY2024.

	Terms as announced on 18 October 2023	Endorsed Amended Terms
Facility amount as at date of announcement	$1,400,000*	$1,400,000
Repayment	By 30 April 2024	By 31 October 2024**
Interest rate	TCV 11am loan interest rate (currently 4.515%)***	TCV 11am loan interest rate (currently 4.515%)***
Security	FY24 RDTI refund	FY24 RDTI refund

* The facility as at 18 October 2023 was $4.0million of which $2million (50% of facility) was paid in the December 2023 quarter and $600,000 (15% of facility) was paid in the March 2024 quarter
** Expected to be repaid upon receipt of 2024FY RDTI
***Any overdue instalment payments may also attract an additional 2% interest.

Net operating cash outflows for the quarter were $1,569,840 ($572,789 net inflow in the prior quarter). Excluding prior quarter inflows of $2,350,940 from the RDTI refund received in the prior quarter, operating cash outflows reduced by $208,311 reflecting completion of the active part of the AD-214 Phase I clinical trial during the period.

The cash balance at the end of the quarter was A$1.51 million (A$3.68 million at the end of the previous quarter), excluding the initial $1.2 million investment under the placement described in the previous section.

In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in item 6.1 of the Appendix 4C were ($120,649) which include Director fees plus the salary (including superannuation) for the CEO and Managing Director.

D. Summary

AdAlta has made exciting progress on multiple strategic initiatives since the half year report. Phase I extension study results for enabled a material acceleration of partnering and co-development discussions to finance Phase II clinical studies and realise the value of this asset. A new collaboration with SYNthesis BioVentures has been established to investigate, over the next 6 months, an exciting opportunity to provide Asian developed cellular immunotherapies with a pathway to western regulated markets via Australia and access to AdAlta's i-body technology for future pipeline projects. And a new institutional investment of up to $3.7 million has provided the working capital need to progress this initiatives and internal discovery programs independent of the outcome and timing of the AD-214 partnering program.

For a video summary of this release and opportunity to engage in a virtual discussion see: https://investorhub.adalta.com.au/link/XyOomy

This ASX announcement has been authorised for release by the Board of AdAlta Limited (ASX:1AD).

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About AdAlta Limited

AdAlta Limited is a clinical stage drug development company headquartered in Melbourne, Australia. The Company is using its proprietary i-body® technology platform to solve challenging drug targeting problems and generate a promising new class of single domain antibody enabled protein and cell therapeutics with the potential to treat some of today's most challenging medical conditions.

The i-body® technology mimics the shape and stability of a unique and versatile antigen binding domain that was discovered initially in sharks and then developed as a human protein. The result is a range of unique proteins capable of interacting with high selectivity, specificity and affinity with previously difficult to access

targets such as G-protein coupled receptors (GPCRs) that are implicated in many serious diseases. i-bodies are the first fully human single domain antibody scaffold and the first based on the shark motif to reach clinical trials.

AdAlta has completed Phase I clinical studies for its lead i-body candidate, AD-214, that is being developed for the treatment of Idiopathic Pulmonary Fibrosis (IPF) and other human fibrotic diseases for which current therapies are sub-optimal and there is a high unmet medical need. The Company is advancing partnering discussions to finance Phase II clinical studies, preparation for which is underway.

The Company is also entering collaborative partnerships to advance the development of its i-body® platform and expand its clinical stage pipeline. It has a collaboration with Carina Biotech to codevelop precision engineered, i-body® enabled CAR-T cell therapies (i-CAR-T) to bring new hope to patients with cancer. It has an agreement with GE Healthcare to co-develop i-bodies as diagnostic imaging agents (i-PET imaging) against Granzyme B, a biomarker of response to immuno-oncology drugs, a program now in preclinical development. It has entered a Memorandum of Understanding with SYNthesis BioVentures to investigate the formation of a jointly owned entity, to be called AdCella, that, once established, will provide innovative cellular immunotherapies originating in Asia with a pathway to western regulated markets via Australian clinical trials and further enhancement with AdAlta's i-body® technology.

AdAlta's strategy is to maximise the products developed using its next generation i-body® platform by discovering and developing selected i-body® enabled product candidates against GPCRs implicated in fibrosis, inflammation and cancer; and partnering with other biopharmaceutical companies to develop product candidates against other classes of receptor, in other indications, and in other product formats.

For more information

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To learn more about AdAlta please click here: www.adalta.com.au

Appendix 4C

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

Name of entity

ADALTA LIMITED

ABN	**Quarter ended ("current quarter")**
92 120 332 925	31 March 2024

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	-	-
1.2	Payments for		
	(a) research and development	(644)	(3,301)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(387)	(1,377)
	(f) administration and corporate costs	(525)	(1,435)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	7	40
1.5	Interest and other costs of finance paid	(20)	(99)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	2,352
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(1,569)**	**(3,820)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	(63)
	(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**	-	**(63)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	3,532
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	-	(270)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(600)	(2,600)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other – (provide details if material)	-	(56)
3.10	**Net cash from / (used in) financing activities**	**(600)**	**606**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	3,682	4,790
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,569)	(3,820)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(63)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(600)	606
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**1,513**	**1,513**

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	347	112
5.2	Call deposits	1,166	3,570
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)**	**1,513**	**3,682**

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	121
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

The amount at 6.1 includes Director fees and CEO and Managing Director salary (including superannuation).

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities	1,400	1,400
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	**1,400**	**1,400**

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.

Loan facility in place as at 31 March 2024 is a non-dilutive funding facility with Treasury Corporation of Victoria (TCV) as part of the Victorian Government's R&D Cash Flow Loan Initiative.

The Company is current finalising an extension of the Treasury Corporation of Victoria (TCV) loan facility (Facility) extended to AdAlta as part of the Victorian Government's R&D Cash Flow Loan Initiative.

The table below outlines the terms of the Facility as announced on 18 October 2023 and the amended terms of as agreed by AdAlta Limited and Invest Victoria. The amendment is subject only to execution of the formal extension agreement by AdAlta Limited and TCV. Full repayment of the facility is expected to be upon receipt of AdAlta's Research and Development Tax Incentive (RDTI) rebate in respect of FY2024.

	Terms as announced on 18 October 2023	**Endorsed Amended Terms**
Facility amount as at date of announcement	$1,400,000*	$1,400,000
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Interest rate	TCV 11am loan interest rate (currently 4.515%)***	TCV 11am loan interest rate (currently 4.515%)***
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* The facility as at 18 October 2023 was $4.0million of which $2million (50% of facility) was paid in the December 2023 quarter and $600,00 (15% of facility) was paid in the March 2024 quarter
** Expected to be repaid upon receipt of 2024FY RDTI
** Any overdue instalment payments may also attract an additional 2% interest.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (Item 1.9)	(1,569)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	1,512
8.3	Unused finance facilities available at quarter end (Item 7.5)	
8.4	Total available funding (Item 8.2 + Item 8.3)	1,512
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	**1.0**

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

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

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: During the quarter ending 31 March 2024 the company incurred significant R&D costs in relation to the completion of the active portion of the Phase 1 extension clinical study and ongoing internal discovery projects. The Company expects June 2024 quarter expenditure to be broadly in line with the March 2024 quarter. Clinical study close out and final payments will substantially complete during the June quarter and thereafter operating cash requirements are anticipated to decrease.

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: Post period end, the Company announced a placement with New Life Sciences Capital and an entity associated with the Meurs Group, a major existing shareholder to raise $1.2 million immediately and up to $3.7 million in total. Also post period end the Company announced the extension of the repayment date of the remaining balance of the Victorian Government RDTI Loan Advance Facility to October 2024 to align with the receipt of the RDTI rebate in respect of the FY24 year. The Company continues to advance partnering discussions for AD-214 which, if successful, could result in material funds inflows. The Company has 73 million listed options expiring 29 May with exercise price $0.03 (current market price $0.031) which if fully exercised would provide additional $5 million funds inflow before costs.

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: As a result of the investment by NLSC and Meurs Group, and the progress of the other initiatives outlined above, the Company anticipates being able to continue its operations and meet its business objectives.

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: 29 April 2024

Authorised 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.