

# June 2023 Activities Report and Appendix 4C

# **Key points:**

- Strong bank balance of \$21.8 million with spending in line with budget
- Experienced global pharmaceutical executive joins Board
- PTX-100 advancing towards Phase 2 clinical trial
- Ongoing progress of OmniCAR and CellPryme platforms
- OmniCAR and CellPryme data showcased at international meeting

**MELBOURNE Australia, 27 July 2023** – Prescient Therapeutics (ASX: PTX), today reported its Appendix 4C quarterly cash flow statement and accompanying Activities Report for the June 2023 quarter.

During the quarter, Prescient continued to advance its targeted cancer therapy PTX-100 through clinical development, whilst advancing the company's cell therapy platforms, CellPryme and OmniCAR. The business continues to make solid progress on all fronts.

#### **Financial summary**

Prescient held cash reserves of \$21.8 million on 30 June 2023 (\$19.9 million held on 31 March 2023) of which \$16 million was term deposits with maturities ranged between 6 months and 12 months. Net operating expenditure during the quarter was \$820,000, in line with budget and with \$1.2 million invested in R&D and clinical development activities.

Prescient has a cash runway of approximately 10.5 quarters based on net cash used during the quarter.

Payments during the quarter to related parties of the entity and their associates amounted to \$169,000 and were directly related to non-executive director fees, executive director salary and superannuation.

# **Prescient Board bolstered with industry veteran**

Prescient continues to attract excellent people to bolster the company's leadership and operations. A highlight of the quarter was the appointment of Dr Ellen Feigal to the Board as a Non-Executive Director.



Dr Feigal is an accomplished industry leader with deep operational experience and understanding of the regulatory and commercial pathways for new cancer therapies.

Dr Feigal is currently a Partner and Head of the Biologics practice at global life sciences advisory firm, NDA Partners LLC, where she leads efforts in designing and executing product development and regulatory strategies in the areas of cell therapies, medical imaging, haematology and oncology. She is also adjunct faculty at the Sandra Day O'Connor College of Law, Arizona State University, where she teaches FDA drug law and medical research ethics and law.

Dr Feigal was formerly Senior Vice President overseeing research and development with the California Institute of Regenerative Medicine, a world-leading research foundation working to accelerate development of new disease modifying treatments and cures for patients with chronic diseases; Executive Medical Director, Global Development at US biotech company Amgen Inc (NASDAQ: AMGN); Vice President of Clinical Sciences at the Translational Genomics Research Institute, and directed the Division of Cancer Treatment and Diagnosis at the National Cancer Institute.

Dr Feigal's deep operational understanding of cancer therapy regulatory pathways, manufacturing and markets will be invaluable as Prescient approaches a clinical inflexion point for PTX-100 and progresses its next-generation cancer therapy platforms, OmniCAR and CellPryme.

## PTX-100 continues to see promising results

The dedicated clinical research team led by principal investigator, Professor H. Miles Prince AM in Melbourne, Australia, continue to report encouraging results from the ongoing Phase 1b trial of PTX-100 in patients with relapsed and refractory T cell lymphomas.

Prof Prince and his team continue to see encouraging clinical activity in this difficult-to-treat patient population, which includes two patients who experienced a total eradication of their cancer, as previously reported. Moreover, the durability of these responses to date are robust, with seven of ten evaluable patients having durable responses exceeding those typically seen using standard of care treatments.

As reported in March, these encouraging responses has led Prescient's clinical and regulatory advisors to recommend enrolling more patients in the ongoing Phase 1b trial.



The aim is to collect additional data to support a formal request to the US Food & Drug Administration (FDA) for a Phase 2 trial.

Concurrently, an additional manufacturing campaign of PTX-100 is being initiated to support the planned Phase 2 study, with the commensurate regulatory documentation required of a potential registration study. Chemistry, manufacturing and control resources in the US have been strengthened to undertake this crucial work.

The Company looks forward to reporting on the progress of this important program in the coming months.

# Ongoing progress of OmniCAR and CellPryme platforms

#### OmniCAR platform development

Steady development continued with OmniCAR platform during this period. Unlike conventional CAR-T therapies, which are "static" constructs, the modular OmniCAR platform enables many desirable control features, including post infusion control of cell activity via binder administration and ability to direct immune cells against a variety of targets sequentially or simultaneously. Therefore, some of the variables that need to be explored and optimized include the number of cells to administer, the doses of binders to administer and the dosing schedule, against a dynamic background of varying cell numbers that expand *in vivo*.

As the OmniCAR platform development advances, Prescient's focus has been to methodically explore these variables that demonstrate the control and flexibility features of the platform, and prepare a robust pre-clinical data set to inform clinical studies. Such data will also be of interest to external parties seeking solutions to overcome the limitations of current CAR-T therapies.

# Favourable results from binder "resting"

During the period, Prescient explored various binder dose levels, as well as the administration schedule of these binders, which has yielded some very valuable results and insights into the performance of OmniCAR.

It is not possible to control the activity of conventional CAR-T cells once they are infused. By contrast, the modularity of the OmniCAR platform permits "pulsed" stimulation of OmniCAR-T cells through timed binder administration. Prescient has now demonstrated that various "resting" periods (i.e. temporary cessation of binder administration) correspond with superior performance of T cell longevity and tumour killing.



This is in keeping with the hypothesis that T cells do not perform optimally when constantly stimulated and become prone to premature exhaustion. By contrast, metronomic stimulation (via timed binder administration) may better simulate the natural cycles of immune cells and result in superior therapeutic performance.

# MD Anderson collaboration

Prescient has had three binders under investigation for the possible treatment of AML: two internal programs using CD33 and CLL-1 binders, and an earlier stage collaboration with the MD Anderson Cancer Center to incorporate a TCR-like binder for AML into OmniCAR. Based on data to date, and the need to prudently manage resources, Prescient has decided to discontinue the latter program at this stage, and thanks MD Anderson for its work. Both parties may seek to revisit the collaboration or consider other opportunities in the future.

## CellPryme further improvement in performance

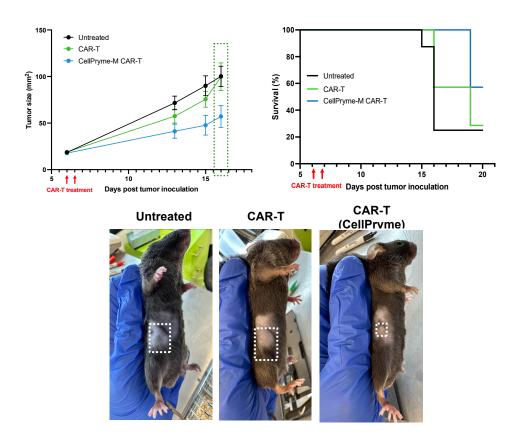
Further optimization was made to CellPryme-M during the period, which improved the already impressive performance of this cell therapy manufacturing enhancement. CellPryme-M is a non-disruptive additive added during cell manufacturing that doubles the effectiveness of CART cells tested to date by making them longer lasting and potent.

Improvements were made to the exposure protocol during cell manufacture, which results in a stable amount of CAR expression on T-cells, and also resulted in a further increase in central memory T-cells (Tcm). Tcm cells are the desired phenotype in CAR-T therapy due their increased longevity and tumour killing properties.

Additional benefits of CellPryme-M were also observed in repeat antigen stimulation models, where CAR-T cells are confronted with repeated doses of fresh tumour, as opposed to a single dose of tumour cells seen in most cancer therapy studies. Such experiments typically exhaust CAR-T cells. Not only did CellPryme-M pretreatment prevent CAR-T exhaustion, but there was also an observed downregulation of immune checkpoints known to enhance the ability of the immune cells to kill cancer.

During the period, CellPryme-M was also successfully demonstrated in an *in vivo* model of colon cancer. In this colon cancer model, a conventional anti-Her2 CAR-T shows very little activity, but when pre-treated with CellPryme-M, exhibits tumour control:





# OmniCAR and CellPryme showcased at prestigious international conference

In June, pre-clinical data from OmniCAR and CellPryme were showcased at the prestigious International Society of Cell & Gene Therapy (ISCT) annual meeting in Paris, France.

Both presentations drew significant interest from cell therapy researchers and industry participants, with data from both platform technologies demonstrating that they are able to address key limitations facing the cell therapy field.

# Active engagement with the international pharma & biotech sector

In addition to ISCT, during the period Prescient attended and presented at a number of key international conferences – some of these focussing on emerging science in various fields within cell therapy and others focussed on business and commercial opportunities.

Despite sector headwinds and subdued market sentiment, Prescient remains very engaged in business development activities, with full meeting schedules at BIO and several other specialist conferences. Prescient's meetings were well received across all these conferences.



and the company continues to build awareness of its programs amongst pharma and biotech companies, researchers and collaborators as data continues to unfold.

These conferences are also important for Prescient to stay up to date on the latest advances in the field of oncology, maintain and grow relationships with key industry players, and to identify value-adding opportunities.

#### Solid progress set to continue

The developments this quarter further underline the steady progress that Prescient continues to make despite challenging sector conditions.

The company has a strong cash position, a world class research, clinical and commercial team and a valuable, diversified pipeline of personalised cancer therapies steadily producing a growing body supportive data.

The team remains optimistic, motivated and focused on delivering effective new therapies to people with cancer, especially those poorly served by current treatments.

# - Ends -

To stay updated with the latest company news and announcements, <u>please update your details</u> on our investor centre.

#### **About Prescient Therapeutics Limited (Prescient)**

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

#### Targeted Therapies

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

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



data in HER2-negative breast cancer and Phase 1b in recurrent or persistent platinum resistant ovarian cancer.

#### **Cell Therapies**

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

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

Prescient is developing OmniCAR programs for next-generation CAR-T therapies for Acute Myeloid Leukemia (AML); Her2+ solid tumours, including breast, ovarian and gastric cancers; and glioblastoma multiforme (GBM).

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

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

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

Find out more at www.ptxtherapeutics.com or connect with us via Twitter @PTX AUS and LinkedIn.

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#### **Disclaimer and Safe Harbor Statement**

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

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

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

**Supplemental COVID-19 Risk Factors** 

Please see our website: Supplemental COVID-19 Risk Factors

# **Appendix 4C**

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

# Name of entity

Prescient Therapeutics Limited		
ABN	.Quarter ended ("current quarter")	
56 006 569 106	30 June 2023	

.Cor	nsolidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(1,254)	(5,122)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(297)	(1,181)
	(f) administration and corporate costs	(669)	(1,975)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	132	346
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	10	1,701
1.8	Other (provide details if material)	-	-
1.9	Net cash from / (used in) operating activities	(2,078)	(6,231)

2.	Cash flows from investing activities	
2.1	Payments to acquire or for:	
	(g) entities	-
	(h) businesses	-
	(i) property, plant and equipment	-

ASX Listing Rules Appendix 4C (17/07/20)

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
	<ul><li>(j) investments in term deposits with maturities longer than 3 months at acquisition</li></ul>	(16,000)	(16,000)
	(k) intellectual property	-	-
	(I) 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	(16,000)	(16,000)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	11,296
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	4,006	5,256
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(685)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	4,006	15,867

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	19,971	12,264
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,078)	(6,231)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(16,000)	(16,000)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	4,006	15,867
4.5	Effect of movement in exchange rates on cash held	(4)	(5)
4.6	Cash and cash equivalents at end of period	5,895*	5,895*

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

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	1,895	7,971
5.2	Call deposits	4,000*	12,000
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	5,895**	19,971

<sup>\*</sup>The call deposits included in item 5.2 above, have maturities ranged between 1 month and 3 months.

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

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	169
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
	if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include ation for, such payments.	e a description of, and an

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
Loan facilities	-	-
Credit standby arrangements	-	-
Other (please specify)	-	-
Total financing facilities	-	-
Unused financing facilities available at qu	arter end	_
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.		
	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.  Loan facilities  Credit standby arrangements  Other (please specify)  Total financing facilities  Unused financing facilities available at qualinclude in the box below a description of each maturity date and whether it is secured or unbeen entered into or are proposed to be entered	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.  Loan facilities -  Credit standby arrangements -  Other (please specify) -  Total financing facilities  Unused financing facilities available at quarter end  Include in the box below a description of each facility above, including maturity date and whether it is secured or unsecured. If any additional been entered into or are proposed to be entered into after quarter end.

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(2,078)
8.2	Cash and cash equivalents at quarter end (item 4.6)	5,895
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	5,895
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	2.8
	Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8	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: N/A
  - 8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

<sup>\*</sup> In addition to the cash and cash equivalents balance noted above at 8.4, the Company holds an additional \$16 million in term deposits, classified in the statement of financial position as short-term investments in accordance with AASB, due to the maturity date being greater than 3 months. As a result, the estimated quarters of funding available will be greater than the figure provided in 8.5 due to holding these additional short-term investments. On a pro-forma basis with the \$16 million included, the Company would have estimated quarters of funding available amounting to 10.5.

- 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?
- 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?

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.

# **Compliance statement**

- 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: 27 July 2023

Authorised by: By the Board

(Name of body or officer authorising release – see note 4)

#### Notes

- 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.
- 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.