



Quarterly Activities &
Cash Report and 4C
For the quarter ended
31 December 2021



IMUGENE

ABN 99 009 179 551

ASX Announcement

Quarterly Activities and Cash Flow Report Quarter ended 31 December 2021

SYDNEY, Australia, 28 January 2022: Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company, is pleased to announce its Quarterly Cash Flow report (Appendix 4C) for the quarter ended 31 December 2021.

Key highlights this quarter included:

- **Clinical trial supply agreement with Merck KGaA (Darmstadt, Germany) and Pfizer Inc. to evaluate HER-Vaxx in combination with avelumab (Bavencio®) for treatment of perioperative gastric cancer**
- **onCARlytics research collaboration with US-based Eureka Therapeutics, Inc. for the treatment of solid tumours**
- **First patients dosed in Phase I clinical trial of CHECKvacc in Triple Negative Breast Cancer**
- **FDA IND approval received for nextHERIZON Phase 2 clinical trial of HER-Vaxx**
- **FDA IND approval received for Phase 1 clinical trial of VAXINIA in solid tumours.**
- **HER-Vaxx patent allowed in China, protecting method of composition and method of use to 2036**
- **Imugene added to the S&P/ASX 200 Index as part of December quarter rebalance**
- **\$118.4m cash balance as at 31 December 2021**
- **Quarterly research and development expenditure was \$6.77m**

HER-Vaxx clinical trial supply agreement with Merck KGaA & Pfizer

Imugene announced during November it had entered a new clinical trial supply agreement with Merck KGaA, Darmstadt, Germany (ETR: MRK) and Pfizer Inc. (NYSE: PFE) to evaluate the safety and efficacy of Imugene's B-cell activating immunotherapy HER-Vaxx, in combination with avelumab, an immune checkpoint inhibitor targeting PD-L1, for patients with HER-2 positive gastric cancer. Marketed as BAVENCIO®, avelumab is co-developed and co-commercialized by Merck KGaA, and Pfizer.

The study, to be known as neoHERIZON, is an open-label, multi-center, randomized, Phase 2 clinical trial designed to assess the safety and efficacy of perioperative HER-Vaxx combined with chemotherapy, with or without avelumab, compared to chemotherapy alone in patients with HER-2 positive gastric or gastroesophageal junction adenocarcinomas. The study's primary endpoint is pathologic complete response. Secondary endpoints include safety and biomarker evaluation.

Under the agreement Imugene will be the sponsor of the study and fund it from existing budgets and resources, with Merck KGaA and Pfizer providing avelumab for the duration of the trial.

onCARlytics: Research collaboration with Eureka Therapeutics

Imugene announced during November it has agreed to a strategic collaboration with Eureka Therapeutics, Inc., a clinical stage biotechnology company developing novel T-cell therapies to treat solid tumours.

Under the agreement Imugene's oncolytic virus onCARlytics technology will be used in combination with Eureka's anti-CD19 ARTEMIS® T-cell therapy for the treatment of solid tumours. The combination has the potential to address a lack of tumour-specific targets for T-cell therapies by using an oncolytic virus to force tumours to express CD19.

Preclinical studies performed at City of Hope Comprehensive Cancer Center combined CAR-T therapy with an oncolytic virus to eliminate tumours in mice, with the virus entering tumour cells, forcing the expression of the CD19 protein on the cell surface and therefore providing a target for anti-CD19 T-cells to pursue and kill.

CHECKvacc: Phase I trial doses first patients

During October world-renowned independent cancer research and treatment center City of Hope® dosed the first patient in a Phase I clinical trial of Imugene's oncolytic virotherapy candidate CHECKvacc.

A first-in-human, Phase I, single-centre dose escalation trial targeting patients with triple negative breast cancer (TNBC), it is aimed at evaluating the safety and initial evidence of efficacy of intra-tumoral administration of CHECKvacc. The current trial design involves dose escalation, followed by an expansion to 12 patients at the final dose, which is the recommended Phase 2 dose level.

In December Imugene announced dosing of the second patient in the trial, following clearance of the required 28-day safety window of the patients dosed in the initial cohort of the study.

CHECKvacc (CF33-hNIS-antiPDL1) is an immune checkpoint inhibitor armed chimeric vaccinia poxvirus from the lab of CF33 inventor Professor Yuman Fong, Chair of Sangiaco Family Chair in Surgical Oncology at City of Hope, and a noted expert in the oncolytic virus field.

FDA IND approvals received for HER-Vaxx and VAXINIA

Imugene received two US Food and Drug Administration (FDA) Investigational New Drug (IND) approvals during the period pertaining to a new Phase 2 trial of immunotherapy candidate HER-Vaxx and a Phase 1 trial of oncolytic virotherapy candidate VAXINIA.

The former allows the Company to commence patient recruitment and dosing for the nextHERIZON study in HER2/neu overexpressing metastatic or advanced adenocarcinoma of the stomach or gastroesophageal junction, also known as Advanced Gastric Cancer (AGC).

The clinical trial is titled "nextHERIZON: An open-label, signal generating, phase 2 study of HER-Vaxx in combination with chemotherapy or pembrolizumab in patients with metastatic HER2/neu overexpressing gastric or gastroesophageal junction (GEJ) adenocarcinomas who have previously received trastuzumab and progressed on this treatment".

The second approval allows Imugene to start patient recruitment and dosing in a Phase 1 clinical trial for the MAST (Metastatic or Advanced Solid Tumors) study in multiple solid tumour type patients.

The clinical trial is titled "A Phase I, Dose Escalation Safety and Tolerability Study of VAXINIA (CF33-hNIS), Administered Intratumorally or Intravenously as a Monotherapy or in Combination with Pembrolizumab in Adult Patients with Metastatic or Advanced Solid Tumors (MAST)".

HER-Vaxx patent granted in China

Imugene received a Notice of Allowance from the People's Republic of China Patent Office for Patent Application number 2016800291184 which protects its HER-Vaxx immunotherapy, currently in development for HER-2 positive gastric cancer.

The patent, titled "A VACCINE COMPOSITION AND USES THEREOF", protects the method of composition and method of use of Imugene's HER-Vaxx immunotherapy to 2036. China has one of the highest incidence rates of gastric cancer worldwide, of which approximately one in five cases are considered HER2 positive. Approximately 75% of all gastric cancer diagnoses are in Asia. Particularly high incidence rates in East Asia make China a very large market for gastric cancer medications.

Imugene added to S&P/ASX 200

During the quarter Imugene was pleased to be added to the S&P/ASX 200 index as part of the December 2021 quarterly rebalance. The change came into effect prior to the open of trade on 20 December 2021.

Financial Update

At the end of the period Imugene has \$118.4 million in cash and cash equivalents, providing ample cash runway to support its clinical pipeline and operations through 2025.

The net cash used in operating activities during the quarter was \$2.2 million compared to \$7.7 million in the previous quarter. The significant change relates to the receipt of the R&D tax refund of \$6.54 million.

Imugene also successfully raised \$8.6 million through the exercise of options during the quarter. The funds will be used to support the Company's commercial and clinical milestones.

The Company continues to monitor its expenditure carefully across all facets of the business, though this is expected to increase as clinical programs ramp up.

In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in items 6.1 of the Appendix 4C include payments for remuneration of director fees to executive and non-executive directors in the normal course of business at commercial rates, excluding reimbursements of out-of-pocket expenses.

Annual General Meeting

Imugene's Annual General Meeting (AGM) was held virtually on Friday 19 November 2021. All resolutions were determined on a poll, with resolutions 1 (Remuneration report) and 3 (Ratification of previous equity issuance) passed, while resolution 2 (Re-election of Director Dr Axel Hoos) was not passed.

The full results of the AGM are available at:

<https://app.sharelinktechnologies.com/announcement/asx/88734fb23a21dca669e8e34c4c3848e3>

The presentation delivered as part of the AGM can be viewed at:

<https://app.sharelinktechnologies.com/announcement/asx/b18883d51355f3679b3ec93e37fb83ed>

Ceasing to be a Director

Following the results of the AGM, Dr Axel Hoos was not re-elected as a Non-Executive Director of the Company, after being appointed in 2013.

On behalf of the Board of Directors, Imugene Chairman Mr Paul Hopper thanks Dr Hoos for his contribution to the Company.

Change of Joint Company Secretary

During the period Mr Nathan Jong was appointed as Joint Company Secretary alongside Phillip Hains. Nathan is a qualified chartered accountant with over ten years of experience in providing finance and corporate compliance advisory services to a range of businesses including multinational ASX and NASDAQ listed companies.

This appointment followed the resignation of Mr Justyn Stedwell as Joint Company Secretary. Justyn was appointed to the role in July 2012 and the Board thanks him for his services.

Events since the end of the Half Year:

4th of Jan, 2022: Imugene enhanced its senior management team with industry leaders Ursula McCurry and Dr. Nimali Withana. Both are former Roche/Genentech employees and experts in oncology clinical development.

4th of Jan, 2022: Imugene completed its Phase 1a monotherapy dose escalation of immunotherapy PD1-Vaxx. The study will now add combination therapy of PD1-Vaxx and atezolizumab (TENCENTRIQ®) in treatment naïve non small cell lung cancer patients to the Phase 1b portion of the on-going clinical trial.

HER-Vaxx immunotherapy received a Notice of Grant from the South Korean Intellectual Property Office for Patent Application number 10-2017-7032987.

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About Imugene (ASX:IMU)

Imugene is a clinical stage immuno-oncology company developing a range of new and novel immunotherapies that seek to activate the immune system of cancer patients to treat and eradicate tumours. Our unique platform technologies seek to harness the body's immune system against tumours, potentially achieving a similar or greater effect than synthetically manufactured monoclonal antibody and other immunotherapies. Our product pipeline includes multiple immunotherapy B-cell vaccine candidates and an oncolytic virotherapy (CF33) aimed at treating a variety of cancers in combination with standard of care drugs and emerging immunotherapies such as CAR T's for solid tumours. We are supported by a leading team of international cancer experts with extensive experience in developing new cancer therapies with many approved for sale and marketing for global markets.

Our vision is to help transform and improve the treatment of cancer and the lives of the millions of patients who need effective treatments. This vision is backed by a growing body of clinical evidence and peer-reviewed research. Imugene is well funded and resourced, to deliver on its commercial and clinical milestones. Together with leading specialists and medical professionals, we believe Imugene's immuno-oncology therapies will become foundation treatments for cancer. Our goal is to ensure that Imugene and its shareholders are at the forefront of this rapidly growing global market.

Release authorised by the Managing Director and Chief Executive Officer

Imugene Limited, Level 3, 62 Lygon Street, Carlton, VIC, 3053, Australia

Appendix 4C

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

Name of entity

Imugene Limited

ABN

99 009 179 551

Quarter ended (“current quarter”)

31 December 2021

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(6,765)	(12,205)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(909)	(2,218)
(f) administration and corporate costs	(1,657)	(2,790)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	55	125
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	6,542	6,542
1.8 Other (provide details if material)	527	628
1.9 Net cash from / (used in) operating activities	(2,208)	(9,920)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	(5)
(d) investments	-	-
(e) intellectual property	-	-
(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)	-	-
2.6	Net cash from / (used in) investing activities	-	(5)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	95,000
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	8,595	11,562
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(6,570)
3.5	Proceeds from borrowings	-	42
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other – repayment of debt	-	(1,361)
3.10	Net cash from / (used in) financing activities	8,595	98,673

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	112,204	29,487
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,208)	(9,920)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(5)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	8,595	98,673
4.5	Effect of movement in exchange rates on cash held	(185)	171
4.6	Cash and cash equivalents at end of period	118,406	118,406

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	68,401	91,203
5.2	Call deposits	50,005	21,001
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)	118,406	112,204

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	251
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>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.</i>		

Item 6.1 – Include payments for remuneration of director fees to executive and non-executive directors in the normal course of business at commercial rates, excluding reimbursements of out-of-pocket expenses.

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

7. Financing facilities	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<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)	-	-
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)	(2,208)
8.2 Cash and cash equivalents at quarter end (item 4.6)	118,406
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	118,406
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	53.6
<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

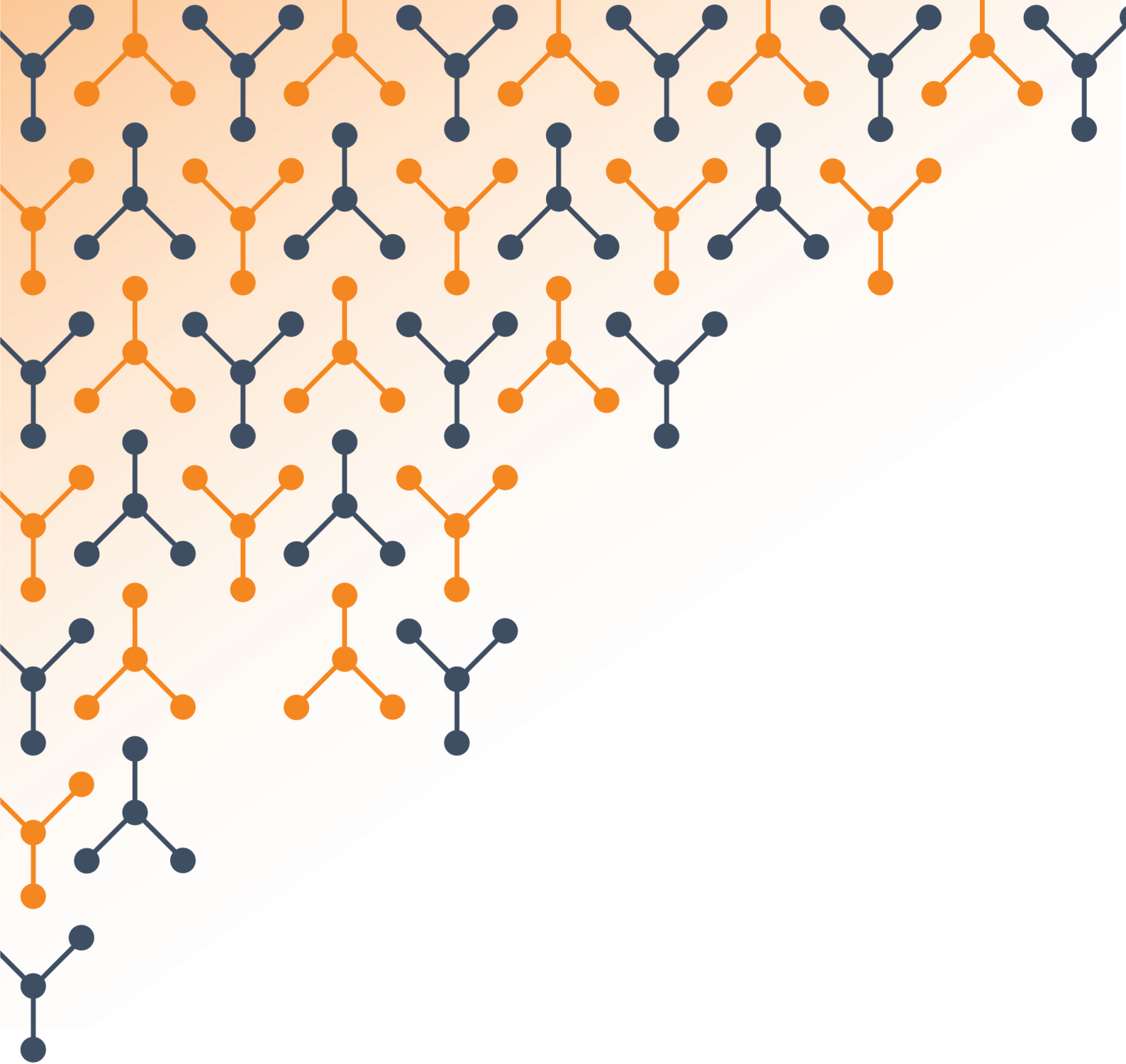
- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 28 January 2022

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.



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