



Quarterly Activities &  
Cash Report and 4C  
For the quarter ended  
**30 September 2021**



**IMUGENE**

ABN 99 009 179 551

## Quarterly Activities and Cash Flow Report Quarter ended 30 September 2021

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**SYDNEY, Australia, 22 October 2021:** 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 30 September 2021.

Key highlights this quarter included:

- **\$90 million Placement and oversubscribed \$5 million Share Purchase Plan Completed to fund Imugene's programs**
- **onCARlytics research collaboration with US-based Celularity Inc., a clinical stage biotechnology company developing off-the-shelf placental-derived allogeneic therapies**
- **US FDA IND approval and first patient dosed (post quarter end) for Phase I clinical trial of oncolytic virotherapy candidate, CHECKvacc**
- **Imugene announced secondary endpoint progression free survival (PFS) data for HER-Vaxx immunotherapy in HER-2 positive gastric cancer**
- **Planning of three new HER-Vaxx Phase 2 studies**
- **HER-Vaxx received patent in Japan, protecting method of composition and method of use to 2036**
- **Imugene added to the S&P/ASX 300 Index as part of September quarter rebalance.**
- **\$112.2m cash balance as at 30 September 2021**
- **Quarterly research and development expenditure was \$5.4m**

### Research collaboration with Celularity

In August, Imugene announced it had entered a research partnership with Celularity Inc. ("Celularity") (NASDAQ: CELU), a clinical-stage biotechnology company developing off-the-shelf placental-derived allogeneic therapies.

As part of the partnership, Imugene and Celularity will initially collaborate to develop the combination of Imugene's CD19 oncolytic virus technology and Celularity's CD19 targeting allogeneic chimeric antigen receptor (CAR) T cellular therapy, CyCART-19, for the treatment of solid tumours. CyCART-19 is a placental-derived T-cell investigational therapy engineered with a CAR that is cryopreserved and will be available off-the-shelf.

Imugene exclusively licensed the CD19 oncolytic virus technology from City of Hope®, a world-renowned independent cancer research and treatment center near Los Angeles. Imugene's novel strategy to treat solid tumours uses an oncolytic virus to prime the tumour cells for destruction by eliciting the expression of a validated tumour marker, CD19, that can then be used as a target for CAR T cellular therapy.

The broad research partnership is material to Imugene as it includes the development of Imugene's onCARlytics CD19 oncolytic virus licensed from the City of Hope® (see ASX announcement dated 18

May 2021) with Celularity's allogeneic CAR T-cell therapy (CyCART-19) and has the potential to become a new approach to improve outcomes for patients with solid tumours.

The research collaboration agreement, effective 5 August 2021, has an initial term of 12 months. Imugene will fund its component of the research partnership from its planned research budget and, hence, no further funding is required for the research partnership. Currently each party has full intellectual property (IP) rights (patents) to their individual background technology. In the event new IP is generated from the research collaboration (each a "Combination Invention"), the parties shall discuss in good faith the filing, prosecution, maintenance, enforcement, defence of any patent applications relating thereto, as well as each party's right to use, such Combination Invention. Following the successful completion of the pre-clinical research, the parties will negotiate in good faith a collaboration agreement on commercially reasonable terms.

## **Update on Clinical Trials**

### **CHECKvacc**

In early July, Imugene announced City of Hope® had received US Food and Drug Administration (FDA) Investigational New Drug (IND) approval to initiate a Phase I clinical trial of its oncolytic virotherapy candidate, CHECKvacc (CF33-hNIS-antiPDL1).

The FDA approval of the IND allows Imugene and City of Hope® to start patient recruitment and dosing in a Phase 1 clinical trial for triple-negative breast cancer (TNBC) patients.

The clinical trial is titled "A Phase I Study of Intratumoral Administration of CF33-hNIS-antiPDL1 in Patients with Advanced or Metastatic Triple Negative Breast Cancer". Principal Investigator Dr. Yuan Yuan, MD PhD is leading the trial.

The study aims to evaluate the safety and initial evidence of efficacy of intra-tumoral administration of CF33-hNIS-antiPDL1 against metastatic TNBC. The trial will involve a dose escalation, followed by an expansion to 12 patients at the final dose, the recommended phase 2 dose (RP2D).

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

Oncolytic viruses (OVs) are designed to both selectively kill tumour cells and activate the immune system against cancer cells, with the potential to improve clinical response and survival.

Post the end of the quarter, Imugene announced that it had dosed the first patient in the Phase I clinical trial of oncolytic virotherapy candidate, CHECKvacc (CF33-hNIS-antiPDL1).

### **PD1-Vaxx**

Imugene's first-in-human, Phase 1, multi-centre, dose escalation study of PD1-Vaxx is recruiting patients with non-small cell lung cancer. Medical investigators are testing three different doses of PD1-Vaxx. Imugene announced three patients had commenced their dosing schedule for the third monotherapy cohort.

The primary goal of the Phase 1 trial is to determine safety and an optimal biological dose as a monotherapy (mOBD). Efficacy, tolerability and immune response will also be measured. Determination of mOBD will be made by the CRC and requires successive dosing within cohorts of at least three patients each.

Imugene's PD1-Vaxx is a B-cell activating immunotherapy designed to treat tumours such as lung cancer by interfering with PD-1/PD-L1 binding and interaction, and produce an anticancer effect similar to Keytruda®, Opdivo® and the other immune checkpoint inhibitor monoclonal antibodies that are transforming the treatment of a range of cancers.

Clinical results continue to indicate that PD1-Vaxx is showing early signs of an immune response in patients, with antibodies to the target biomarker PD-1 evident in validated assays.

Imugene is planning to expand the study to combine PD1-Vaxx with standard of care (SOC) therapy in the same lung cancer patient population. This may include a PD-L1 inhibitor or another immunotherapy agent. Inclusion criteria will allow patients that have either progressed on their previous therapy or did not have a response to their SOC and are at high risk of progression to enter the study. Additionally, PD1-Vaxx is currently being evaluated for other tumour indications beyond non small cell lung cancer (NSCLC).

Full study details can also be found on clinicaltrials.gov under study ID: NCT04432207.

Imugene presented on its PD1-Vaxx cancer checkpoint immunotherapy program at the ESMO Congress 2021 Annual Meeting in Paris on 17 September 2021.

The presentation is titled 'IMPRINTER: AN OPEN LABEL, MULTI-CENTER, DOSE ESCALATION/EXPANSION, PHASE I STUDY OF IMU-201 (PD1-VAXX), A B-CELL IMMUNOTHERAPY, IN ADULTS WITH NON-SMALL CELL LUNG CANCER'.

Presentation content is available on the Imugene website under Conference Presentations.

## **HER-Vaxx**

In September, Imugene announced secondary endpoint progression free survival (PFS) data for its HER-Vaxx immunotherapy in HER-2 positive gastric cancer.

Imugene's Phase 2 HER-Vaxx clinical trial is designed to evaluate the efficacy, safety, and immune response in metastatic gastric cancer overexpressing the HER-2 protein. The study is randomised into two arms of either HER-Vaxx plus standard-of-care (SOC) chemotherapy or SOC chemotherapy alone. The primary endpoint is overall survival (OS) and secondary endpoint includes PFS by independent central review. A total of 36 patients were enrolled in the Phase 2 trial and 24 achieved a PFS event in this signal generating study. Imugene is awaiting the events needed for OS evaluation and will subsequently analyse all data including final OS, PFS, safety, and immune responses.

The centrally confirmed secondary PFS endpoint, which was designed with a specified one-sided false positive probability of 0.10, analysis showed a hazard ratio (HR) of 0.719 with a 1-sided p-value of 0.266 between the HER-Vaxx plus SOC chemotherapy treatment arm compared to the SOC chemotherapy control arm. There was no difference in safety between the two treatment arms, showing HER-Vaxx does not add toxicity to SOC chemotherapy, with detailed safety analysis to be conducted once the trial is completed.

Imugene's PFS HR was comparable to the landmark Genentech/Roche registrational ToGA study (PFS HR of 0.71), which also examined the effect of Herceptin plus chemotherapy versus SOC chemotherapy alone in advanced HER-2 positive gastric cancer.

Based on these results, Imugene is planning three further Phase 2 studies with HER-Vaxx in early and late stage gastric cancer.

Imugene's HER-Vaxx is a B-cell activating immunotherapy designed to treat tumours that overexpress the HER-2/neu receptor, such as gastric, breast, ovarian, lung and pancreatic cancers. The

immunotherapy is constructed from several B cell epitopes derived from the extracellular domain of HER-2/neu. It has been shown in pre-clinical studies, in Phase I and now Phase 2 studies to stimulate a potent polyclonal antibody response to HER-2/neu, a well-known and validated cancer target.

The HERIZON Phase 2 trial, which has completed recruitment, is being conducted at multiple sites across Eastern Europe and India where clinicians have difficulty accessing approved antibody treatments such as Herceptin®.

Imugene presented on the HER-Vaxx cancer immunotherapy program at the ESMO World Congress on Gastrointestinal Cancer 2021 Annual Meeting in early July.

The abstract presentation was entitled 'HERIZON: A PHASE 1B/2 OPEN-LABEL STUDY OF IMU-131 HER2/NEU PEPTIDE VACCINE PLUS STANDARD OF CARE CHEMOTHERAPY WITH RANDOMIZATION IN PHASE 2 IN PATIENTS WITH HER2/NEU OVEREXPRESSING METASTATIC OR ADVANCED ADENOCARCINOMA OF THE STOMACH OR GASTROESOPHAGEAL JUNCTION' Updated Interim Analysis Results.

The presentation expanded on previously presented interim analysis data presented at AACR2021.

#### *Patent in Japan*

Imugene received notice in September of a Notice of Grant from the Japanese Patent Office for Patent Application number 2018-505505 which protects its HER-Vaxx immunotherapy, currently in development for HER2 positive gastric cancer.

The patent titled "A VACCINE COMPOSITION AND USES THEREOF" (inventor Professor Dr Ursula Wiedermann from the Medical University Vienna) protects the method of composition and method of use of Imugene's HER-Vaxx immunotherapy to 2036.

Approximately 75% of all gastric cancer diagnoses are in Asia. Japan has the third highest incidence rate of gastric cancer worldwide, of which approximately one in five cases are considered HER2 positive. This makes Japan a very large market for gastric cancer medications<sup>1</sup>.

#### **Placement and Share Purchase Plan**

Imugene received firm commitments from institutional and sophisticated investors for a \$90 million placement of 300 million new fully paid ordinary shares (New Shares) in the Company at a price of \$0.30 per share (Placement), as announced on 29 July 2021.

The Placement received outstanding support from several specialist biotech institutional investors who corner stoned the capital raising.

Imugene announced a Share Purchase Plan ("SPP") to raise up to \$5 million to follow the Placement.

Under the Placement and SPP, participants received one (1) free option for every two (2) shares subscribed for under the offer (New Options). The New Options have an exercise price of \$0.45 per share and an expiration of 31 August 2024.

The SPP was strongly supported by eligible shareholders and was heavily oversubscribed, successfully raising its target of A\$5.0 million. Under the SPP, 16.7 million ordinary shares were issued at \$0.30 each on 20 August 2021, together with 8.3 million attaching options. The options are exercisable at \$0.45 each at any time on or before 31 August 2024.

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<sup>1</sup> GLOBOCAN 2018 Graph production: IARC. World Health Organization. August 2020.

The funds raised provide an adequate cash runway for Imugene's range of programmes through to the end of 2025, with partnering and licensing opportunities and R&D rebates having the potential to extend the runway further. The capital raise will fund clinical trials for HER-Vaxx, PD-1-Vaxx, CHECKvacc, Vaxinia and OnCARlytics, as well as associated manufacturing, regulatory and working capital costs.

The Placement was conducted under Imugene's existing placement capacity pursuant to ASX Listing Rule 7.1 and was led by Bell Potter Securities Limited.

### **Addition to S&P/ASX 300 Index**

Imugene was added to the S&P/ASX 300 Index during the quarter as part of the September quarterly review. Its addition became effective on the open of trading on 20 September 2021.

### **Cash Flow**

At the end of the period Imugene has \$112.2 million in cash and cash equivalents, providing ample cash runway to support its clinical pipeline and operations through 2025.

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.

### **Results of Extraordinary General Meeting**

At an EGM on 7 September 2021, Imugene shareholders passed all resolutions put to the meeting via a poll. Resolutions were as follows:

1. Ratification of issuance of Consideration Shares to unrelated Vaxinia Vendors
2. Approval of allotment and issue of Consideration Shares to related parties: Paul Hopper and persons and entities related to him.

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Follow us on Twitter @TeamImugene  
Like us on Facebook @Imugene  
Connect with us on LinkedIn @Imugene Limited

### **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")**

30 September 2021

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(5,440)	(5,440)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(1,309)	(1,309)
(f) administration and corporate costs	(1,133)	(1,133)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	70	70
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	101	101
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(7,712)</b>	<b>(7,712)</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	(5)	(5)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-



Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 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>(5)</b>	<b>(5)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	95,000	95,000
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	2,967	2,967
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(6,570)	(6,570)
3.5	Proceeds from borrowings	42	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)	(1,361)
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>90,078</b>	<b>90,078</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	29,487	29,487
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(7,712)	(7,712)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(5)	(5)

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	90,078	90,078
4.5	Effect of movement in exchange rates on cash held	356	356
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>112,204</b>	<b>112,204</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	91,203	8,486
5.2	Call deposits	21,001	21,001
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>112,204</b>	<b>29,487</b>

<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	602
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

<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. 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)	-	-
<b>7.4 Total financing facilities</b>	-	-
<b>7.5 Unused financing facilities available at quarter end</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.		
N/A		

<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)	(7,712)
8.2 Cash and cash equivalents at quarter end (item 4.6)	112,204
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	112,204
<b>8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	14.5
<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

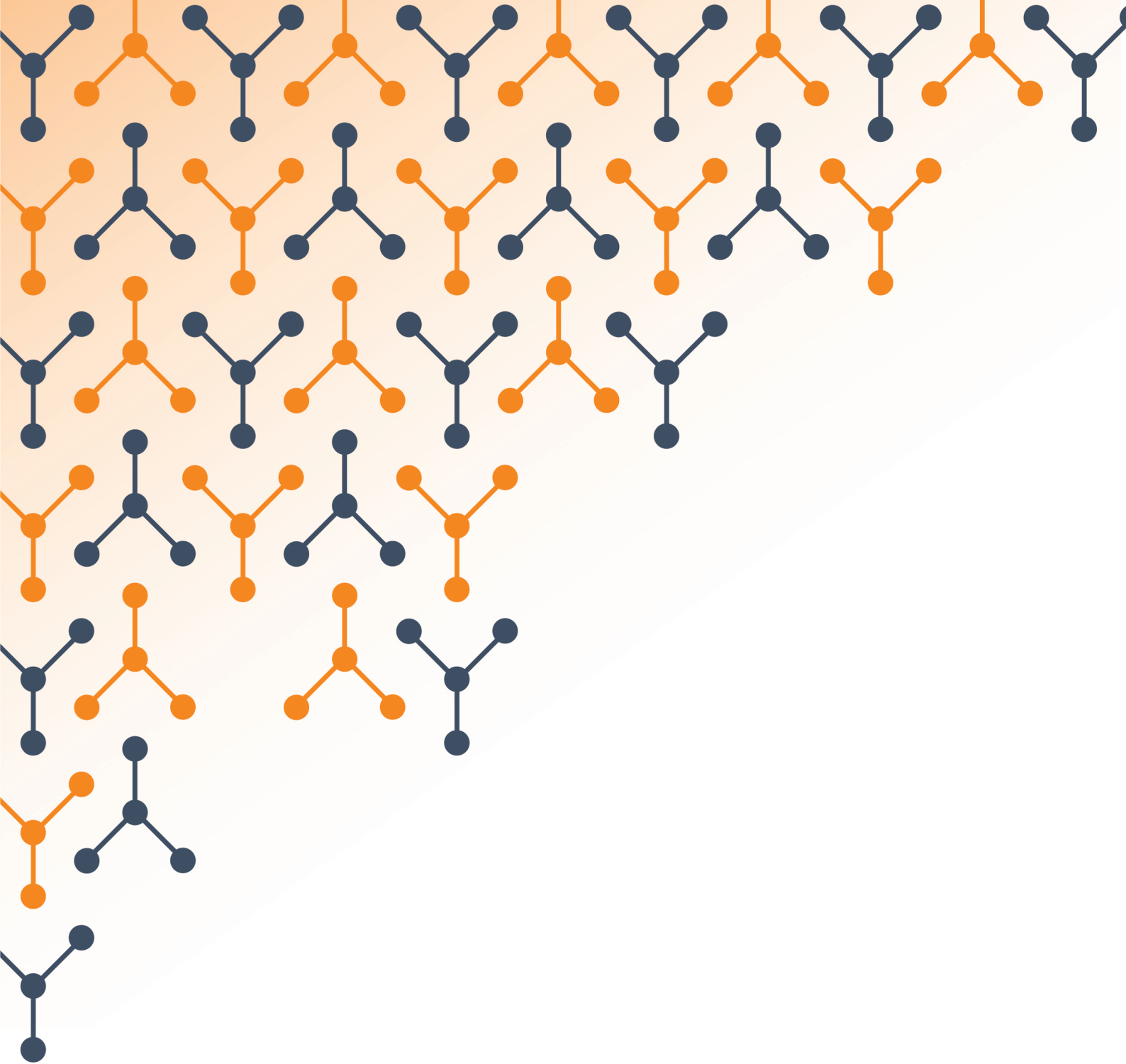
- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 22 October 2021

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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30 September 2021



**IMUGENE**