



**IMUGENE**

Developing Cancer  
Immunotherapies

ASX: IMU

**QUARTERLY ACTIVITIES  
& APPENDIX 4C CASH  
REPORT**

Quarter Ended:  
30 September 2022

For personal use only



**Imugene Limited**  
**ABN 99 009 179 551**

[www.imugene.com](http://www.imugene.com)

## ASX Announcement

### Quarterly Activities and Cash Flow Report

Quarter ended 30 September 2022

---

- **First Patient Dosed in nextHERIZON Phase 2 clinical trial**
- **First Patient Dosed in cohort 3 of Oncolytic Virotherapy CHECKvacc Phase I Clinical Trial**
- **Dose Escalated to cohort 2 in IT arm; first patient dosed in IV cohort 1 in the Phase 1 clinical trial of Oncolytic Virus VAXINIA;**
- **Licence granted allowing VAXINIA Phase 1 trial expansion in Australia**
- **New preclinical trial announced with Arovella's iNKT cell therapy and Imugene's onCARlytics (CF33-CD19) platform**
- **\$80 million raised in institution Placement to provide runway for pipeline of clinical programmes and corporate growth opportunities**
- **Numerous new key management appointments announced**

**SYDNEY, Australia, 28 October 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 30 September 2022.

#### **First Patient Dosed in nextHERIZON Phase 2 clinical trial**

During September, the Company announced that the first patient was dosed in the nextHERIZON Phase 2 clinical trial investigating Imugene's immunotherapy candidate HER-Vaxx in combination with chemotherapy or pembrolizumab in patients with HER-2+ gastric cancer.

The patient was dosed at the Queen Elizabeth Hospital in Adelaide, with additional study sites to be opened.

The open-label, multi-center, signal generating, Phase 2 clinical trial is designed to assess the safety and efficacy of HER-Vaxx in combination with chemotherapy or pembrolizumab in patients with metastatic HER-2/neu overexpressing gastric or gastroesophageal junction adenocarcinomas, who have previously progressed on trastuzumab. The study's primary endpoints are safety and response rate, while secondary endpoints include duration of response, progression free survival, overall survival, and biomarker evaluation.

#### **First Patient Dosed in Cohort 3 in the Phase I Clinical Trial of Oncolytic Virotherapy CHECKvacc**

In August, the Company announced that City of Hope® had dosed the first patient in cohort 3 in the Phase I clinical trial of oncolytic virotherapy candidate CHECKvacc (CF33-hNIS-antiPDL1). The first-in-human, Phase



1, single-centre, dose-escalation study of CHECKvacc is recruiting patients with triple negative breast cancer (TNBC) and seeks to evaluate the safety and initial evidence of the efficacy of intra-tumoural administration of CF33-hNIS-antiPDL1 against metastatic TNBC.

The trial design involves a dose escalation, followed by an expansion to 12 patients at the final dose, which will be the recommended phase 2 dose (RP2D).

#### **Dose escalation in Phase 1 Clinical Trial of VAXINIA; first patient dosed in intravenous cohort 1**

In September, the Company's Phase 1 MAST (metastatic advanced solid tumours) study evaluating the safety of novel cancer-killing virus CF33-hNIS (VAXINIA) reached critical milestones in the trial. The opening of cohort 2 for intratumoral (IT) administration followed the clearing of IT cohort 1, while intravenous cohort 1 (IV) opened in parallel.

In addition, the Cohort Review Committee (CRC) unanimously agreed that VAXINIA is safe, with no dose-limiting toxicities (DLTs) and no serious adverse reactions observed. The CRC advised the Company to proceed with opening the second VAXINIA Phase 1 cohort at the mid-dose level following the completion of the review meeting.

The multicenter Phase 1 trial commenced with delivering a low dose of VAXINIA to patients with metastatic or advanced solid tumours with at least two prior lines of standard of care treatment.

Later in the month, Imugene announced that the first patient of the IV cohort 1 of the trial had been dosed.

A multicenter Phase 1 trial, the VAXINIA Phase 1 MAST study has to date delivered a low dose to patients with metastatic or advanced solid tumours who have had at least two prior lines of standard of care treatment. The study aims to recruit 100 patients across approximately 10 trial sites in the United States and Australia.

Also during September, the Australian Government Office of the Gene Technology Regulator (OGTR) granted Imugene the DIR licence required to expand the trial within Australia. The licence, numbered DIR 192 and titled 'Clinical trial of a genetically modified (GM) chimeric Orthopoxvirus (CF33-hNIS) as a cancer treatment', is required as part of the Australian regulatory framework for dealings involving the intentional release of genetically modified organisms into the environment.



## **New preclinical trial of Arovella's iNKT cell therapy and Imugene's onCARlytics (CF33-CD19) platform to explore potential in solid tumours**

Later in September, Imugene jointly announced with Arovella Therapeutics Ltd (ASX: ALA) that Arovella's CAR19-iNKT cell therapy platform would be tested with Imugene's onCARlytics platform to seek and destroy solid tumours. The readout from the preclinical studies performed through the collaboration is expected in H1 2023.

Imugene is evaluating a range of CD19 targeting therapies in combination with onCARlytics of which Arovella's ALA-101 will be included, allowing Arovella to benchmark its iNKT therapy for solid tumour treatment.

Arovella's lead iNKT product, ALA-101, contains a Chimeric Antigen Receptor (CAR) that targets tumour cells producing CD19 on their surface. Typically, CD19 expression is on the cell surface of blood cancers. Imugene's onCARlytics platform enables solid tumour cancers to express CD19 on their surface, which creates the opportunity to use ALA-101 to seek and destroy the solid tumour cells. Currently, ALA-101 is being developed for CD19-producing blood cancers. Working with Imugene raises the possibility of using ALA-101 to treat solid tumour cancers.

## **PD1-Vaxx Data Presented at 2022 World Conference on Lung Cancer**

Imugene announced in August that data from non-small cell lung cancer patients in the Phase 1 IMPRINTER trial was presented as a poster presented at the IASLC World Conference on Lung Cancer. Professor Michael Boyer M.D., MBBS, FRACP, PhD, Chris O'Brien Lifehouse Hospital presented the poster, titled "Phase 1: IMU-201 (PD1-Vaxx), a B-Cell Immunotherapy as Monotherapy or in Combination with Atezolizumab, in Adults with Non-Small Cell Lung Cancer.

## **\$80 million institutional Placement**

In September, the Company announced that it had received firm commitments for an \$80 million Placement at \$0.20 per share led by two leading institutional investors with significant healthcare and biotechnology expertise. The funds raised have provided an extended runway for Imugene's deep pipeline of clinical programmes and corporate growth opportunities.

## **Management Appointments**

Imugene appointed Mike Tonroe as Chief Financial Officer in September. Mr Tonroe has extensive experience as a CFO and Company Secretary within the biopharmaceutical industry. He also brings international finance leadership experience, having worked in the US, Canada, UK and Hong Kong, and Australia. Most recently, Mr Tonroe was CFO and Company Secretary at ASX-listed Opthea Limited and Genetic Technologies Limited, and before that was in the same role for private business Australian Synchrotron Company Ltd. These tenures included management of the US IPO and NASDAQ listing of Opthea



along with M&A, restructuring, capital raising and leading the finance function across these businesses. Adding to the depth of Mr Tonroe's experience, he has exposure to the technology, energy and travel sectors from earlier roles, including time with major accounting firms KPMG and Deloitte.

In September, Imugene announced the appointment of Dr Jakob Dupont as a Non-Executive Director. Dr Dupont is an industry and drug development expert with more than 20 years of experience specialising in oncology and other therapeutic areas. Dr Dupont's experience includes NASDAQ-listed Atara Biotherapeutics (NASDAQ: ATRA), where he oversaw all research and development, including three clinical stage programs spanning Phase 1 through to Phase 3, and numerous preclinical programs.

The accomplished Dr Sharon Yavrom joined the Company as Executive Director, Clinical Scientist in July. Dr Yavrom is a clinical scientist with nearly 20 years of industry experience, holding positions at industry leading companies such as TAP Pharmaceuticals, Amgen and BMS.

### **Financial Update**

At the end of the period Imugene has \$163.8 million in cash or equivalents, providing a runway to support its clinical pipeline and operations into 2027.

Net cash used in operating activities for the quarter amounted to \$12.2 million, with direct Research and Development and Staff costs accounting for over 91%.

Imugene also successfully raised \$80 million through a successful institutional placement. 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. Options granted to directors that are included in Imugene's Remuneration Report under share-based payments, are non-cash amounts and represent valuations using the Black-Scholes methodology. Share-based payments relating to option grants to directors are therefore not included in item 6.1 of the Appendix 4C.



## Post Balance Activities

Following the end of the reporting period Imugene was pleased to announce that its onCARlytics (CF33-CD19) oncolytic virus technology will be featured in three abstracts at the renowned Annual Meeting for the Society for Immunotherapy of Cancer (SITC), to be held in Boston, USA on 8-12 November 2022.

Imugene also announced an abstract regarding the overall survival results from its HER-Vaxx HERIZON study has been accepted for an oral presentation at the ESMO Asia Congress 2022 being held in Singapore 2-4 December 2022.

In October, Dr Giovanni Selvaggi joined Imugene as Chief Medical Officer. A pulmonologist trained in thoracic malignancies with a focus on lung cancers and mesothelioma, he has over a decade of experience in the pharmaceutical industry. Dr Selvaggi held a pivotal role in Novartis successful development and approval of ceritinib (or Zykadia, targeting non-small cell lung cancer/NSCLC) and was part of the immunotherapy team at Bristol Myers Squibb that led to the approval of nivolumab (Opdivo) in third line small cell lung cancer.

Also in October, Paul Wright was appointed to the role of Vice President CMC (Chemistry, Manufacturing and Controls). Mr Wright is an accomplished bioprocess development leader with over 25 years of experience in the fields of protein and virus production. He spent 21 years at Pfizer holding positions of increasing responsibility within the Global Manufacturing and Vaccine Research and Development organisations. Most recently he led a team responsible for the process, analytical, and formulation development of cancer vaccine projects from preclinical to first-in-human study stage.

For more information please contact:

**Leslie Chong**

**Managing Director and Chief Executive Officer**

info@imugene.com

**Investor Enquiries**

investor@imugene.com

**Media Enquiries**

Matt Wright

matt@nwrcommunications.com.au

Follow us on Twitter @TeamImugene

Like us on Facebook @Imugene

Connect with us on LinkedIn @Imugene Limited

View us on YouTube @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 2022

<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	(8,697)	(8,697)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(2,405)	(2,405)
(f) administration and corporate costs	(1,251)	(1,251)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	72	72
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)	89	89
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(12,192)</b>	<b>(12,192)</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	-	-
(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>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	80,000	80,000
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	239	239
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(5,283)	(5,283)
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 – repayment of debt	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>74,956</b>	<b>74,956</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	99,888	99,888
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(12,192)	(12,192)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	74,956	74,956
4.5	Effect of movement in exchange rates on cash held	1,163	1,163
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>163,815</b>	<b>163,815</b>

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	134,808	70,888
5.2	Call deposits	29,007	29,000
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>163,815</b>	<b>99,888</b>

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	724
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.

<b>7. Financing facilities</b>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i>		
<i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 <b>Total financing facilities</b>	-	-
7.5 <b>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)	(12,192)
8.2 Cash and cash equivalents at quarter end (item 4.6)	163,815
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	163,815
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	13.4
<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 October 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.

For personal use only



**IMUGENE**

Developing Cancer  
Immunotherapies

ABN 99 009 179 551

[www.imugene.com](http://www.imugene.com)