

Developing Cancer Immunotherapies

**ASX: IMU** 

## QUARTERLY ACTIVITIES & APPENDIX 4C CASH REPORT

Quarter Ended: 31 December 2024

> Imugene Limited ABN 99 009 179 551

> > www.imugene.com



## **ASX Announcement**

## **Quarterly Activities and Cash Flow Report**

### Period ended 31 December 2024

- Bile tract cancer patient in MAST trial maintains a complete response for over two years; bile tract cancer expansion cohort is open, enrolling up to 10 patients
- Phase 1 onCARlytics trial doses first patient in intratumoural (IT) combination arm
- First Australian site opens for Phase 1b azer-cel trial, recruiting patients that have relapsed or refractory from autologous CAR T with diffuse large B-cell lymphoma (DLBCL)
- Azer-cel research accepted for presentation at the 2025 ASTCT Tandem Meetings.
- Issuance of convertible notes & warrants to CVI Investments, raising \$20 million, and an additional \$26 million if warrants are exercised
- \$11.7 million R&D tax refund received for FY23 in January 2025

**SYDNEY, Australia, 31 January 2025:** 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 2024.

#### **CLINICAL TRIAL UPDATES**

## Bile Tract Cancer Patient maintains Complete Response in MAST Study for Over Two Years

The December quarter saw a significant milestone in the Company's Phase 1 MAST (Metastatic Advanced Solid Tumours) trial evaluating CF33-hNIS (VAXINIA). A bile tract cancer patient has maintained a complete response (CR) for over two years, demonstrating the potential durability of this novel oncolytic virotherapy.

In addition, Imugene announced the Bile Tract Cancer Expansion cohort of the MAST trial cleared its first group of three patients, with no dose-limiting toxicities observed, and opened for enrolment of up to 10 patients.



Finally, it was also announced a patent extension for CF33's method of composition and use was granted in the US, extending its protection until 2040. This strengthens the intellectual property for VAXINIA and other therapies within the CF33 platform.

#### Phase 1 onCARlytics Trial Doses First Patient in Intratumoural (IT) Combination Arm

In November, the first patient was dosed in the intratumoural (IT) combination arm of Imugene's Phase 1 onCARlytics (CF33-CD19) clinical trial, OASIS. The trial, conducted at 8 U.S. oncology centres including Northwestern University, Emory, Roswell Park and MD Anderson Cancer Center aims to evaluate the safety and efficacy of Imugene's CD19expressing oncolytic virotherapy in advanced or metastatic solid tumours.

The OASIS trial involves up to 40 patients and explores two routes of administration, IT injection and intravenous (IV) infusion. The therapy, onCARlytics, is currently being tested in combination with the CD19-targeting drug blinatumomab. By enabling solid tumours to express CD19, onCARlytics enables targeting by established and validated CD19 therapies, a significant innovation for treating "targetless" tumours.

This milestone follows the first patient dosing in the IV monotherapy arm earlier this year and represents continued progress in developing advanced treatments for hard-to-treat solid tumours.

#### First Australian site for azer-cel Phase 1b clinical trial

Imugene opened the first Australian site for its Phase 1b clinical trial of azer-cel (azercabtagene zapreleucel), an allogeneic CAR T-cell therapy targeting CD19 for relapsed or refractory diffuse large B-cell lymphoma (DLBCL). The Royal Prince Alfred Hospital in Sydney began patient recruitment in November 2024, making it the only actively enrolling allogeneic CAR T trial in Australia. In early January of 2025, the first patient was enrolled in Australia.



The trial has already shown promising initial results at US sites, with three complete responses reported, including two from patients in Cohort B who were treated with azer-cel, lymphodepletion (chemotherapy), and interleukin-2 (IL-2). These responses were durable, extending beyond 90 and 120 days. Azer-cel offers an on demand, off-the-shelf alternative to traditional autologous CAR T therapies, addressing logistical challenges, extended time to manufacturing and expanding accessibility.

Imugene plans to open up to five sites in Australia to accelerate enrolment and provide access to this innovative therapy for patients with limited treatment options.

Azer-cel will continue to enrol patients into Cohort B as patients treated with azer-cel, lymphodepletion (chemotherapy), and interleukin-2 (IL-2) have shown promising initial results.

#### Azer-cel accepted for presentation at ASTCT Tandem Meetings event

During the quarter, Imugene announced that an abstract on azer-cel has been accepted for a poster presentation at the 2025 Tandem Meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for International Blood and Marrow Transplant Research (CIBMTR). The event, which highlights advancements in hematopoietic cell transplantation, cellular therapy, and gene therapy, will take place from February 12-15, 2025, in Hawaii.

The poster, titled "Administration of Low-Dose, Subcutaneous (SC) Interleukin-2 (IL-2) Markedly Enhances the Pharmacokinetic (PK) Profile of Azercabtagene Zapreleucel (azer-cel), an Allogeneic Anti-CD19 Chimeric Antigen Receptor (CAR) T-Cell Therapy, without Compromising Safety and Early Evidence of Clinical Activity in Patients with Diffuse Large B-Cell Lymphoma (DLBCL) Who Have Relapsed after Prior CD19-Directed CAR T-Cell Products", will be presented by Dr. Joseph Maakaron of the University of Minnesota during a session on February 13, 2025.

The research demonstrates azer-cel's enhanced pharmacokinetics with low-dose IL-2 administration while maintaining safety and showing early clinical activity in relapsed



DLBCL patients. This recognition reflects the progress of Imugene's CAR T-cell therapy pipeline targeting blood cancers.

#### **B-cell Immunotherapy**

The HER-Vaxx program has been completed and the studies are closed.

Imugene presented on the HER-Vaxx cancer immunotherapy program at the San Antonio Breast Cancer Symposium (SABC) on 12 December 2024.

The poster presentation was entitled 'Tumor Size Reduction And Overall Survival Improvement in HER2-Overexpressing Gastric Cancer Patients Vaccinated with HER-Vaxx, a B-cell Peptide-based Vaccine, Plus Standard-of-Care Chemotherapy'.

Imugene also presented final HERIZON results at the European Society of Medical Oncology Congress Meeting in late September 2024.

The abstract presentation was entitled 'Final results of the Phase II trial of HER-Vaxx, a Bcell peptide-based vaccine plus standard care of chemotherapy, in patients with HER2overexpressing advanced gastric cancer - (HERIZON)'

PD1-Vaxx will be used to support a Phase 2, Investigator Sponsored Trial (IST) known as Neo-POLEM which will start in the first half of 2025. The trial is expected to recruit approximately 40 patients with colorectal cancer in Australia and the UK, whereby PD1-Vaxx will be administered before surgery (neoadjuvant).

As previously stated, the B-cell immunotherapies have been deprioritized to focus on the azer-cel and Oncolytic Virus programs.

Management continues to pursue out-licensing opportunities for its B-cell immunotherapies.



#### CORPORATE

#### Retirement of Jens Eckstein as Non-Executive Director

At November's AGM, it was announced that Jens Eckstein would resign from his position as a Non-Executive Director of Imugene. Having been a member of the board since May 2019, Imugene thanks him for his service.

#### **FINANCIALS**

# Issuance of Convertible Notes & Warrants to CVI Investments Inc. to raise up to A\$46 million

In December, the Company entered into a funding agreement with CVI Investments, Inc., to raise up to \$46 million through the issuance of convertible notes and warrants. The agreement includes \$20 million in senior unsecured zero-coupon convertible notes with a five-year maturity and up to an additional \$26 million from five-year unlisted warrants, exercisable at \$0.0494 per share.

The convertible notes will initially be convertible into Imugene shares at a 25% premium to the company's closing price on December 20, 2024, with semi-annual price adjustments. The funds will support ongoing clinical trials for key programs, including azer-cel, onCARlytics, and VAXINIA, and will extend Imugene's cash runway to the end of 2025, excluding any additional warrant exercises.

This financing structure is expected to strengthen Imugene's ability to progress its immuno-oncology pipeline while avoiding traditional interest and security costs associated with other funding mechanisms. Additional operational optimisations are in place to further extend the company's financial resources.

#### \$11.7 million R&D tax refund received for FY23

Following the end of the quarter Imugene announced it had received its R&D tax refund for the 2023 financial year, totaling \$11,689,963 (including interest of \$514,093).



#### **Cashflow report**

At the end of the December quarter Imugene has \$33.7 million in cash or equivalents. This excludes a total of \$31.7 million received in January 2025: 2023 R&D tax rebate of \$11.7 million and Convertible Note proceeds of \$20 million. The pro-forma cash balance including these receipts is \$65.4 million providing a cash runway to support its clinical pipeline and operations to the end of 2025. Net cash used in operating activities for the quarter amounted to \$16.8 million, with direct research and development costs accounting for 67% (of total costs). Payments of one-off research and development costs in respect of manufacturing processes were \$3.3 million in the quarter.

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.

For more information please contact:

Leslie Chong Managing Director and Chief Executive Officer info@imugene.com

**General Investor Enquiries** shareholderenquiries@imugene.com

**Media Enquiries** Matt Wright matt@nwrcommunications.com.au



Connect with us on LinkedIn @Imugene Limited Follow us on Twitter @TeamImugene Watch us on YouTube @ImugeneLimited

#### 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 pipeline includes an off-the-shelf (allogeneic) cell therapy CAR T drug azer-cel (azercabtagene zapreleucel) which targets CD19 to treat blood cancers. Our pipeline also 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 novel cancer therapies that are currently marketed globally. 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.

## Appendix 4C

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

Name of entity	
Imugene Limited	
ABN	Quarter ended ("current quarter")
99 009 179 551	31 December 2024

Con	isolidated 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	(11,317)	(28,433)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing	(5)	(66)
	(d) leased assets		
	(e) staff costs	(4,686)	(9,600)
	(f) administration and corporate costs	(1,827)	(4,327)
1.3	Dividends received (see note 3)		
1.4	Interest received	667	1,337
1.5	Interest and other costs of finance paid		
1.6	Income taxes paid		(69)
1.7	Government grants and tax incentives		
1.8	Other (provide details if material)	318	318
1.9	Net cash from / (used in) operating activities	(16,851)	(40,840)

2.	Cash flows from investing activities		
2.1 Payments to acquire or for:			
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment	(82)	(11,464)
	(d) investments		
	(e) intellectual property		
	(f) other non-current assets	(4,761)	(7,751)

ASX Listing Rules Appendix 4C (17/07/20) + See chapter 19 of the ASX Listing Rules for defined terms.

Con	solidated 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	1,490	1,490
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	(3,353)	(17,726)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)		
3.2	Proceeds from issue of convertible debt securities		
3.3	Proceeds from exercise of options		2
3.4	Transaction costs related to issues of equity securities or convertible debt securities		
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 lease liability)	(296)	(470)
3.10	Net cash from / (used in) financing activities	(296)	(468)

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	54,257	93,108
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(16,851)	(40,840)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(3,353)	(17,726)

Con	solidated 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)	(296)	(468)
4.5	Effect of movement in exchange rates on cash held	(16)	(333)
4.6	Cash and cash equivalents at end of period	33,742	33,742

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	23,742	4,592
5.2	Call deposits	10,000	49,665
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)	33,742	54,257

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	342
6.2	Aggregate amount of payments to related parties and their associates included in item 2	
	f any amounts are shown in items 6.1 or 6.2, your quarterly activity report must includ ation for, such payments.	e a description of, and an

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.

7.	<b>Financing facilities</b> Note: the term "facility' includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the sources of finance available to the entity.	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1	Loan facilities		
7.2	Credit standby arrangements		
7.3	Other (please specify)		
7.4	Total financing facilities		
7.5	Unused financing facilities available at qu	arter end	
7.6	.6 Include in the box below a description of each facility above, including the lender, inter- 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.		itional financing

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(16,851)
8.2	Cash and cash equivalents at quarter end (item 4.6)	33,742
8.3	Unused finance facilities available at quarter end (item 7.5)	
8.4	Total available funding (item 8.2 + item 8.3)	33,742
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	2.00
	Note: if the entity has reported positive net operating cash flows in item 1.9, answer it figure for the estimated quarters of funding available must be included in item 8.5.	em 8.5 as "N/A". Otherwise, a
8.6	If item 8.5 is less than 2 quarters, please provide answers to the follow	owing questions:
	8.6.1 Does the entity expect that it will continue to have the curren cash flows for the time being and, if not, why not?	t level of net operating
	Answer: N/A	
	8.6.2 Has the entity taken any steps, or does it propose to take an cash to fund its operations and, if so, what are those steps a believe that they will be successful?	
	Answer:	
	N/A	
	8.6.3 Does the entity expect to be able to continue its operations a objectives and, if so, on what basis?	nd to meet its business
	Answer: N/A	
	Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 ab	ove must be answered.

#### **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: 31 January 2025

Authorized by	Executive Chair
Authorised by:	(Name of body or officer authorising release – see note 4)

#### f

#### 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.