

Developing Cancer Immunotherapies

**ASX: IMU** 

## QUARTERLY ACTIVITIES & APPENDIX 4C CASH REPORT

Quarter Ended: 30 June 2024

> Imugene Limited ABN 99 009 179 551

> > www.imugene.com



## **ASX Announcement**

## Quarterly Activities and Cash Flow Report Period ended 30 June 2024

- Cash position of \$93 million as at 30 June 2024 (Excluding R&D tax rebate of ~\$11 million expected)
- Four Phase 1/1b/2 clinical trials recruiting in US, Australia and the UK
- Azer-cel continues recruitment in the Phase 1b study
- Phase 1 CF33-hNIS (VAXINIA) bile tract cancer (cholangiocarcinoma) trial opened
- First patient dosed in the IV combination arm of the Phase 1 onCARlytics clinical trial targeting advanced solid tumours
- VAXINIA results presented at the 2024 Cholangiocarcinoma Foundation Annual Conference

**SYDNEY, Australia, 31 July 2024**: Imugene Limited (ASX:IMU), a clinical-stage immunooncology company, is pleased to announce its Quarterly Cash Flow report (Appendix 4C) for the quarter ended 30 June 2024.

### **CLINICAL TRIAL UPDATES**

### Azer-cel continues to enrol in the Phase 1b study.

Azer-Cel (azercabtagene zapreleucel) is an off-the-shelf (allogeneic) cell therapy which targets CD19 to treat blood cancers.

The Phase 1b allogeneic (allo) CAR T study is an ongoing multi-centre clinical trial in patients who suffer from a difficult to treat sub-set of non-Hodgkin's lymphoma (NHL) called Diffuse-Large B-cell lymphoma (DLBCL) that have relapsed after autologous CAR T therapy. These DLBCL patients have limited therapeutic options and are an unmet medical need.

Following completion of the Phase 1b study there is potential to start a registrational Phase 2/3 study in 2025 and become the first approved allogeneic CAR T cell therapy for cancer.



# VAXINIA Bile Tract Cancer trial opened, and the VAXINIA MAST trial higher dose cohort opened for enrolment.

Imugene launched its Phase 1 bile tract cancer (cholangiocarcinoma) trial, which aims to enrol 10 patients. In the Phase 1 MAST trial, one patient with bile tract cancer who had failed three prior lines of therapy received a mid-dose of IT-administered monotherapy VAXINIA, achieved a complete response, meaning the disappearance of all signs of cancer in response to treatment, and the patient has been in the trial for over 630 days. A second patient with bile tract cancer (cholangiocarcinoma), who has also progressed on prior drug therapies, achieved stable disease, meaning their cancer neither increased nor decreased and no new tumours appeared for more than four months upon receiving IVadministered VAXINIA. The results seen in these patients provided the rationale for Imugene to open a VAXINIA trial in this specific patient population.

The FDA granted Fast Track Designation to the VAXINIA program in November 2023, accelerating the development and potential approval process due to the urgent need for new treatments. The MAST trial, which began by administering low doses to patients with advanced solid tumours, has progressed through several dose escalation cohorts without safety concerns. This bile tract cancer trial not only supports the ongoing evaluation of VAXINIA's efficacy, but also emphasizes its role in addressing the significant challenges associated with treating bile tract cancer, an aggressive form cancer with limited effective treatments for patients.

Subsequent to the end of the quarter, Imugene announced that the first patient had been dosed at St. Vincent's Hospital in Melbourne. Additionally, it was confirmed that the fifth cohort of both arms of the Phase 1 MAST monotherapy dose escalation trial have now cleared, with the sixth high dose cohort of each arm having opened.

## Imugene Phase 1 onCARlytics trial doses first patient in Intravenous (IV) combination arm in the OASIS trial.

Late in the quarter, the first patient was dosed in the intravenous (IV) combination arm of the Company's Phase 1 onCARlytics clinical trial. The trial, known as OASIS, is pioneering in



its combination of a CD19-expressing oncolytic virus with a CD19-targeting drug called BLINCYTO® (blinatumomab). CD19 is used in blood cancers, but solid cancers like breast, lung, gastric, bile tract, and colon, etc. don't have a common target on their cell surface; the goal of onCARlytics is to present a target for CD19 therapies. The CD19-expressing CF33 oncolytic virus marks or paints the tumour target with CD19 on the cell surface, followed by treatment with a CD19 targeting therapy. The trial aims to recruit 40-45 patients with advanced solid tumours and is currently being conducted at three sites in the US, with the potential to expand to 10 sites.

The first patient, who has bile tract cancer, was dosed at City of Hope in California. The primary objective of the trial is to evaluate the safety and efficacy of onCARlytics when administered either intratumorally (IT) or intravenously (IV), alone or in combination with blinatumomab, a CD19-targeting bispecific monoclonal antibody.

Preliminary early combination data are expected in the fourth quarter of 2024, subject to patient enrolment rates. If successful, onCARlytics could significantly expand the market for CD19-targeting therapies. CD19 therapies are currently only approved in blood cancers, which only make up 10 percent of cancers, while solid cancers make up 90 percent of the cancer market. If successful onCARlytics could make CD19 targeted therapies an option to treat patients with solid cancers. This could potentially impact a market which is estimated to be valued at approximately US\$532 billion by 2032.

### **CORPORATE UPDATES:**

## Imugene and Kincell Bio Announce Strategic Manufacturing and Process Development Partnership for azer-cel.

In April, Imugene and Kincell Bio established a strategic partnership focused on manufacturing and process development. Under this agreement, Kincell Bio acquired Imugene's manufacturing facility in North Carolina.



Additionally, this strategic shift ensures continued clinical supply of azer-cel, Imugene's advanced allogeneic CAR T cell therapy while Imugene retains all rights to azer-cel.

## VAXINIA selected for Oral and Poster Presentations at 2024 Cholangiocarcinoma Foundation Annual Conference.

Imugene presented its VAXINIA technology at the 2024 Cholangiocarcinoma Foundation Annual Conference in April in Salt Lake City, Utah. In both an oral and a poster presentation, the company discussed the effectiveness and safety of VAXINIA as a treatment for gastrointestinal malignancies, including bile tract cancer (cholangiocarcinoma), highlighting its potential as a monotherapy treatment in a field where early detection and treatment options are limited. This conference provides a platform for healthcare professionals and researchers to exchange insights on advancing the treatment and understanding of bile tract cancer.

### Presentation at Bell Potter Emerging Leaders Conference.

Imugene CEO & Managing Director Leslie Chong presented at the Bell Potter Emerging Leaders Conference in May 2024.

A copy of the presentation can be viewed here.

### **FINANCIALS**

At the end of the June quarter Imugene has A\$93.1 million in cash or equivalents (Excluding R&D tax rebate of ~\$11 million expected imminently), providing a runway to support its clinical pipeline and operations into late 2025. Net cash used in operating activities for the quarter amounted to A\$19 million, with direct research and development costs accounting for 57% of total costs. 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.

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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 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 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.

## Appendix 4C

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

Name of entity	
Imugene Limited	
ABN Quarter ended ("current quarter")	
ABN	Quarter ended ("current quarter")

Con	isolidated 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	(10,936)	(50,170)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing		
	(d) leased assets		
	(e) staff costs	(6,140)	(27,768)
	(f) administration and corporate costs	(2,831)	(22,207)
1.3	Dividends received (see note 3)		
1.4	Interest received	876	4,404
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)		218
1.9	Net cash from / (used in) operating activities	(19,030)	(95,524)

2.	Cash flows from investing activities		
2.1	Payments to acquire or for:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment	(1,896)	(9,360)
	(d) investments		
	(e) intellectual property		
	(f) other non-current assets		(5,543)

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 (12 months) \$A'000
2.2	Proceeds from disposal of:		
	(a) entities		
	(b) businesses	1,434	1,434
	(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	(462)	(13,469)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	(620)	53,013
3.2	Proceeds from issue of convertible debt securities		
3.3	Proceeds from exercise of options		11
3.4	Transaction costs related to issues of equity securities or convertible debt securities	148	(2,735)
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)	(611)	(611)
3.10	Net cash from / (used in) financing activities	(1,083)	49,678

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	114,084	153,151
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(19,030)	(95,524)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(462)	(13,469)

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(1,083)	49,678
4.5	Effect of movement in exchange rates on cash held	(401)	(728)
4.6	Cash and cash equivalents at end of period	93,108	93,108

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	43,535	64,602
5.2	Call deposits	49,573	49,481
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)	93,108	114,084

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	392
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	larter end	
7.6	Include in the box below a description of eac rate, maturity date and whether it is secured facilities have been entered into or are propo include a note providing details of those facil	or unsecured. If any add osed to be entered into af	itional financing

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(19,030)
8.2	Cash and cash equivalents at quarter end (item 4.6)	93,108
8.3	Unused finance facilities available at quarter end (item 7.5)	
8.4	Total available funding (item 8.2 + item 8.3)	
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	5
	Note: if the entity has reported positive net operating cash flows in item 1.9, answer i figure for the estimated quarters of funding available must be included in item 8.5.	tem 8.5 as "N/A". Otherwise, a
8.6	If item 8.5 is less than 2 quarters, please provide answers to the foll	owing questions:
	8.6.1 Does the entity expect that it will continue to have the current cash flows for the time being and, if not, why not?	nt 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 objectives and, if so, on what basis?	and 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 al	oove 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.

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

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#### 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.