



IMUGENE

Developing Cancer
Immunotherapies

ASX: IMU

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

Quarter Ended:
31 March 2024

For personal use only



Imugene Limited
ABN 99 009 179 551

www.imugene.com

ASX Announcement

Quarterly Activities and Cash Flow Report

Quarter ended 31 March 2024

- First patients dosed in Phase 1 MAST trial high dose cohort
- VAXINIA (CF33-hNIS) bile tract cancer expansion trial opened
- First patient dosed in intravenous (IV) monotherapy arm of onCARlytics trial, with trial advancing to combination arm treatment
- Presentations at the 42nd Annual J.P. Morgan Healthcare Conference and ASCO-GI
- Subsequent to the end of the quarter:
 - Divestment of manufacturing facility to Kincell Bio, which will provide substantial savings
 - Presentations at Cholangiocarcinoma Foundation Annual Conference and AACR Annual Meeting
 - CF33 oncolytic virus patent granted in China

SYDNEY, Australia, 30 April 2024: 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 March 2024.

The period under review has been active across all fronts of the Company's technologies.

Clinical Trial Updates

1. Azer-cel: Allogeneic CAR T cell therapy

- Allogeneic, or off-the-shelf, CAR T-cell therapy, uses T cells from healthy donors, making the treatment immediately available to patients, more potent, and less expensive than current approved autologous CAR T treatments
- Phase 1 clinical trial completed in 84 patients dosed with azer-cel



- Currently recruiting Phase 1b trial in patients with diffuse large B cell lymphoma (DLBCL) who relapsed following autologous CAR T therapy
- Trial being conducted in 15 sites in the US, with plans to open up to 5 sites in Australia
- A preliminary early data update is anticipated in the second half of 2024
- Pre-clinical studies are combining azer-cel with Imugene's onCARlytics (CF33-CD19)

2. VAXINIA MAST Trial

- The engineered VAXINIA virus selectively replicates itself in tumor cells, causing the cell to rupture, releasing new virus particles capable of infecting other tumor cells, and promoting anti-tumor immunity
- The Phase 1 MAST trial assesses the safety and efficacy of VAXINIA administered alone, or in combination with pembrolizumab and dosed both intravenously (IV) or intratumorally (IT) in a dose escalation study
- 47 heavily pre-treated patients have been dosed to date (24 April 2024¹), of which 40 patients are evaluable meaning they received at least their first scan at day 42
- Nearly half of the evaluable patients (48%) have remained on treatment for more than 3 months, representing significant disease control; 3 monotherapy patients have remained on treatment for over 200 days
- During dose escalation, one patient with bile tract cancer who failed 3 prior treatments achieved a complete response (CR), which has continued for almost 1.5 years (532 days); 2 patients with melanoma achieved partial responses (PRs), and 17 patients achieved stable disease (SD) while in the trial
- The MAST trial continues to advance and has progressed to higher dose cohorts
- Bile tract cancer expansion trial opened and is expected to enroll approximately 10 patients; preliminary early data is expected in the second half 2024
- The trial is recruiting across 8 sites in the US and 2 sites in Australia
- The company received US FDA Fast Track Designation for bile tract cancer in November 2023, which allows for faster review

¹Preliminary enrollment update; data and number of evaluable patients subject to change with full statistical analysis



3. OnCARlytics (CF33-CD19)

- onCARlytics is a CD19-expressing oncolytic virus (CF33) that enters tumor cells and forces them to express the CD19 protein on the cell surface, presenting a target for CD19 targeting therapies
- The Phase 1 OASIS trial is a world-first in combining onCARlytics (a CD19-expressing oncolytic virus) with CD19 targeted therapy (blinatumomab, Blincyto®), which is an immunotherapy (antibody) that helps fight acute lymphoblastic leukemia (ALL)
- The Cohort Review Committee (CRC) observed no safety issues in the onCARlytics monotherapy lead-in trial and recommended opening the combination arm of the trial
- 3 sites (City of Hope, University of Cincinnati and MD Anderson Cancer Center) are currently open in the US with the potential to open a total of 10 sites to recruit approximately 40-45 patients with advanced solid tumors
- Initiated dosing in the intravenous (IV) monotherapy arm of the trial, with the first patient with bile tract cancer receiving treatment at City of Hope in California
- Preliminary early combination data are expected in the fourth quarter of 2024
- CD19-targeted agents are currently approved for the treatment of blood cancers yet solid tumors make up 90 percent of the cancer market; if successful onCARlytics could make CD19 targeted therapies an option to treat patients with solid tumors

4. B Cell Immunotherapy: PD1-Vaxx

- PD1-Vaxx is a B-cell immuno-therapy which aims to induce the body to produce polyclonal antibodies which block PD-1 signaling, and thus produce an anticancer effect
- The Phase 1 trial, known as Neo-POLEM, will recruit in sites in Australia and the UK
- The trial is expected to recruit approximately 44 patients with colorectal cancer
- Treatment with PD1-Vaxx will be administered before surgery (neoadjuvant)
- Preliminary early data are expected in 2025



5. B Cell Immunotherapy: HER-Vaxx

- HER-Vaxx is a B-cell immuno-therapy designed to treat tumours that over-express the HER-2/neu receptor, such as gastric, breast, ovarian, lung and pancreatic cancers
- Business development discussions are ongoing

Corporate Updates

Strategic Partnership with Kincell Bio

- In April, Imugene and Kincell Bio announced a strategic partnership including the sale of Imugene's manufacturing facility in North Carolina to Kincell Bio for up to \$6 million USD in upfront and milestone payments
- The transaction is expected to yield Imugene approximately A\$49.0 million (USD\$32 million) in cost savings from salaries, drug manufacturing, and overhead costs
- While Imugene retains all rights to azer-cel, Kincell Bio will take over the manufacturing of azer-cel, thus allowing the Imugene team to focus on the development of novel cancer treatments

Oncolytic Virus CF33 Patent Granted in China

- In April, Imugene's oncolytic virotherapy CF33, including VAXINIA (CF33-hNIS) and CHECKvacc (CF33-hNIS-antiPDL1), was granted a patent in China, the largest Asian pharmaceutical market
- This patent, titled "CHIMERIC POXVIRUS COMPOSITION AND USES THEREOF," secures the method of composition and use of these therapies until 2037
- This follows previous patent grants in Japan and South Korea, reinforcing Imugene's intellectual property portfolio in significant healthcare markets across Asia



Scientific and Healthcare Conference Presentations

2024 Cholangiocarcinoma Foundation Annual Conference

- In April, Imugene delivered both an oral and a poster presentation on its CF33-hNIS (VAXINIA) technology, which showcased the encouraging clinical responses of VAXINIA as a monotherapy for treating gastrointestinal cancers, including cholangiocarcinoma

Association for Cancer Research (AACR) Annual Meeting

- In April, Daneng Li, MD, from the City of Hope National Comprehensive Cancer Centre, presented a poster demonstrating that oncolytic virus CF33-hNIS (VAXINIA) alone or in combination with pembrolizumab is a safe treatment option for advanced cancer patients.
- In April, Joshua Tobias Ph.D., presented a poster demonstrating that compared to chemotherapy alone, vaccination with HER-Vaxx was associated with a 40% overall survival benefit

Gastrointestinal (GI) Cancers Symposium (ASCO-GI)

- In January, Daneng Li, MD, from the City of Hope National Comprehensive Cancer Centre, presented a poster demonstrating that CF33-hNIS (VAXINIA) monotherapy may be an effective and safe treatment option for GI (gastrointestinal) malignancies and warrants further investigation in biliary tract cancer patients

J.P. Morgan Healthcare Conference

- In January, CEO Leslie Chong, presented at the 42nd Annual J.P. Morgan Healthcare Conference, one of the largest and most prestigious events on the healthcare and biotechnology industry calendar each year, with more than 8,000 investors, senior industry professionals and government officials in attendance at the 2023 event
- Interested parties can view a recording of the presentation at:
<https://t.co/nEHJHsjm0Z>



Financials

At the end of the March quarter Imugene has \$114.1 million in cash or equivalents, providing a runway to support its clinical pipeline and operations. Net cash used in operating activities for the quarter amounted to \$25.2 million, with direct research and development costs accounting for 49% 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.

For more information please contact:

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

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 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

99 009 179 551

Quarter ended ("current quarter")

31 March 2024

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(12,442)	(39,234)
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs	(9,322)	(21,628)
(f) administration and corporate costs	(4,741)	(19,376)
1.3 Dividends received (see note 3)		
1.4 Interest received	1,076	3,528
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	218
1.9 Net cash from / (used in) operating activities	(25,212)	(76,494)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities		
(b) businesses		
(c) property, plant and equipment		(7,464)
(d) investments		
(e) intellectual property		
(f) other non-current assets		(5,543)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 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	0	(13,008)
3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)		53,633
3.2	Proceeds from issue of convertible debt securities		
3.3	Proceeds from exercise of options	11	11
3.4	Transaction costs related to issues of equity securities or convertible debt securities		(2,883)
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)		
3.10	Net cash from / (used in) financing activities	11	50,761
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	139,392	153,151
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(25,212)	(76,494)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	0	(13,008)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	11	50,761
4.5	Effect of movement in exchange rates on cash held	(108)	(327)
4.6	Cash and cash equivalents at end of period	114,084	114,084

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	64,602	90,002
5.2	Call deposits	49,481	49,389
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)	114,084	139,392

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	648
6.2	Aggregate amount of payments to related parties and their associates included in item 2	

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.

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. Financing facilities <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>	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 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.		

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(25,212)
8.2 Cash and cash equivalents at quarter end (item 4.6)	114,084
8.3 Unused finance facilities available at quarter end (item 7.5)	
8.4 Total available funding (item 8.2 + item 8.3)	114,084
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	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: 30 April 2024

Authorised by: Executive Chairman
(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.