IMUGENE

Developing Cancer Immunotherapies

ASX: IMU

QUARTERLY ACTIVITIES & APPENDIX 4C CASH REPORT

Quarter Ended:

30 September 2024

Imugene Limited

ABN 99 009 179 551

www.imugene.com

IMUGENE
Developing Cancer Immunotherapies

ASX Announcement

Quarterly Activities and Cash Flow Report

Period ended 30 September 2024

- Three complete responses achieved in the azer-cel Phase 1b trial for DLBCL
- The trial will continue enrolling patients in cohort B with plans to use the findings for a potential FDA Phase 2 trial for azer-cel
- FDA Orphan Drug Designation received for VAXINIA to treat bile tract cancer
- First patient dosed in Phase 1 bile tract cancer expansion trial at St. Vincent's Hospital, Melbourne, with 10 patients to be enrolled
- Cash position of $53.3 million as at 30 September 2024 (Excluding 2023 R&D tax rebate)

SYDNEY, Australia, 31 October 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 30 September 2024.

CLINICAL TRIAL UPDATES

Three Complete Responses in azer-Cel Allogeneic CD19 CAR T Phase 1b Trial in Blood Cancer (Diffuse Large B-Cell Lymphoma)

Imugene announced encouraging results from its ongoing Phase 1b clinical trial of azer-cel (azercabtagene zapreleucel), an allogeneic CD19 CAR T-cell therapy designed for patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), a particularly aggressive form of non-Hodgkin's lymphoma.

The trial, conducted across 15 leading cancer centers in the US, and with plans to expand into Australia, aims to address a critical unmet need; patients who have relapsed after multiple prior treatments, including autologous CAR T-cell therapy, a standard approach for treating DLBCL.

So far, 10 patients have been treated, divided into two cohorts:

- **Cohort A –** consisting of six patients who received azer-cel alongside lymphodepletion chemotherapy.
- **Cohort B –** involving four patients who received the same treatment but with an additional low dose of interleukin 2 (IL-2), a cytokine that supports the survival and effectiveness of T-cells.

The trial has yielded three complete responses (CRs):

- Two patients in Cohort B, who received the combination of azer-cel and IL-2, achieved complete responses. Their responses have shown durability, with one patient maintaining a complete response for over 120 days and another for over 90 days.
- One patient in Cohort A also achieved a complete response, with durability of response less than 60 days.

Notably, all patients in Cohort B remain in the trial, and an additional patient is currently awaiting evaluation. Given the robust and durable response rates observed in Cohort B, Imugene will continue enrolling more patients into this cohort, closely monitoring their outcomes. The company also plans to incorporate these findings into a registrational package for a potential FDA Phase 2/3 trial, with the ultimate goal of securing approval for azer-cel.

Imugene CEO Leslie Chong hosted a webinar to discuss the results. Click here to view the replay.

Imugene receives Orphan Drug Designation for treatment of Bile Tract Cancer

In September, Imugene announced that it has been granted Orphan Drug Designation (ODD) by the US Food and Drug Administration (FDA) for its novel oncolytic virotherapy, CF33-hNIS (also known as VAXINIA). The designation applies to the treatment of cholangiocarcinoma, a rare and aggressive form of bile tract cancer.

This designation is significant as it provides a range of regulatory and financial incentives, including tax credits, potential grant funding, waiver of certain administrative fees, and most notably, seven years of market exclusivity upon FDA approval.

Cholangiocarcinoma is a malignancy with limited therapeutic options and a high unmet clinical need. The FDA grants Orphan Drug status to drugs intended to treat rare diseases affecting fewer than 200,000 people in the US, encouraging development in areas where treatment is scarce.

Imugene's application for ODD was supported by preclinical and clinical data from its ongoing Phase 1 MAST (Metastatic Advanced Solid Tumours) trial, which is evaluating the safety and efficacy of VAXINIA. The trial has already delivered promising results, with the therapy selectively targeting and destroying cancer cells, while also stimulating an immune response against tumours.

First patient dosed in Phase 1 bile tract cancer trial

In July, the Company dosed the first patient in its Phase 1 expansion study focused on bile tract cancer (cholangiocarcinoma) patients, which took place at St Vincent's Hospital in Melbourne, Australia. This is an extension of the ongoing MAST Phase 1 trial and will enrol 10 patients with cholangiocarcinoma.

In November 2023, the FDA granted the VAXINIA MAST clinical program Fast Track Designation for the treatment of bile tract cancer, which allows Imugene closer cooperation with the FDA to expedite the program and potential approval process.

Bile tract cancer is a rare disease in which malignant cancer cells form in the bile ducts. It is difficult to treat and generally responds poorly to immunotherapy drugs.

INTELLECTUAL PROPERTY

During the quarter the Company received a patent allowance in Brazil for its B-cell immuno-therapy technology HER-Vaxx (Patent No. US 10,532,090 B2).

FINANCIALS

At the end of the September quarter Imugene has $54.3 million in cash or equivalents (excluding 2023 R&D tax rebate), providing a runway to support its clinical pipeline and operations. Net cash used in operating activities for the quarter amounted to $24 million, with direct research and development costs accounting for 71% (of total costs) and a milestone payment to Precision Biosciences for $14.4 million.

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")**
99 009 179 551	30 September 2024

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers		
1.2	Payments for		
	(a) research and development	(17,116)	(17,116)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing	(61)	(61)
	(d) leased assets		
	(e) staff costs	(4,914)	(4,914)
	(f) administration and corporate costs	(2,500)	(2,500)
1.3	Dividends received (see note 3)		
1.4	Interest received	670	670
1.5	Interest and other costs of finance paid		
1.6	Income taxes paid	(69)	(69)
1.7	Government grants and tax incentives		
1.8	Other (provide details if material)		
1.9	**Net cash from / (used in) operating activities**	**(23,989)**	**(23,989)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment	(11,382)	(11,382)
	(d) investments		
	(e) intellectual property		
	(f) other non-current assets	(2,990)	(2,990)

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)		
2.6	**Net cash from / (used in) investing activities**	**(14,373)**	**(14,373)**

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	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)	(174)	(174)
3.10	**Net cash from / (used in) financing activities**	**(172)**	**(172)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	93,107	93,107
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(23,989)	(23,989)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(14,373)	(14,373)

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)	(172)	(172)
4.5	Effect of movement in exchange rates on cash held	(317)	(317)
4.6	**Cash and cash equivalents at end of period**	**54,257**	**54,257**

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	4,592	43,535
5.2	Call deposits	49,665	49,573
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)**	**54,257**	**93,107**

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	344
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** *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 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)	(23,989)
8.2	Cash and cash equivalents at quarter end (item 4.6)	54,257
8.3	Unused finance facilities available at quarter end (item 7.5)	
8.4	Total available funding (item 8.2 + item 8.3)	54,257
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	2.3

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.

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

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.

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 October 2024

Authorised by: .By the Audit and Risk Committee
(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.