



IMUGENE

Developing Cancer
Immunotherapies

ASX: IMU

QUARTERLY ACTIVITIES & APPENDIX 4C CASH FLOW REPORT

Quarter Ended:
31 December 2023



Imugene Limited
ABN 99 009 179 551

www.imugene.com

ASX Announcement

Quarterly Activities and Cash Flow Report

Quarter ended 31 December 2023

- Major VAXINIA catalysts including positive early data & US FDA Fast Track Designation for bile duct cancer
- First patient dosed in Phase 1 trial for onCARlytics
- Commencement of Phase 1b trial for azer-cel
- Phase 2 neoadjuvant neoPOLEM clinical trial (with PD1-Vaxx) to open in 2024 for colorectal cancer patients in the UK and Australia
- Strategic partnership announced with NeoImmuneTech around NI-I7 use with azer-cel
- Imugene recognised with presentations at JP Morgan Healthcare Conference and ESMO Congress

SYDNEY, Australia, 31 January 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 December 2023.

A major quarter of developments for VAXINIA

During November Imugene welcomed early data from the Phase 1 MAST (Metastatic Advanced Solid Tumours) trial of VAXINIA, with positive early signals reported.

At the time of the announcement in November, 2023, 34 heavily pre-treated patients had been dosed with VAXINIA, with 16 receiving intratumoural administration and 18 receiving intravenous dosing, either as a monotherapy or in combination with pembrolizumab.

Among the most notable outcomes was a Complete Response observed in a patient with advanced bile duct cancer and a Partial Response in a patient with advanced melanoma. These results are particularly encouraging, considering the complexities associated with



treating these cancer types. Additionally, there was 16 instances of Stable Disease, further highlighting the potential of VAXINIA as an effective treatment option in oncology.

Most significant though were the results from gastrointestinal cancer patients in the trial, leading Imugene to plan a trial expansion of 10 to 20 patients with bile duct cancers, which are notoriously difficult to treat.

Managing Director and CEO Leslie Chong and Chief Medical Officer Dr Paul Woodard hosted an investor webinar to discuss the results. A replay is available at:

<https://www.youtube.com/watch?v=k9AUCLiQI2o>

In a key regulatory development that followed, VAXINIA received Fast Track Designation for bile duct cancer from the US Food and Drug Administration (FDA). This designation is a testament to the therapy's potential to meet significant unmet medical needs in cancer treatment. Fast Track Designation is pivotal as it facilitates expedited review processes, potentially speeding up VAXINIA's journey towards approval and availability to patients.

The above-mentioned Phase 1 MAST trial continued to progress during the quarter as new cohorts were reached in both the monotherapy dose escalation and combination arms of the study.

onCARlytics Phase 1 clinical trial underway

In October, the Company announced the commencement of its Phase 1 clinical trial for CD19 oncolytic virotherapy drug candidate, onCARlytics. The first patient in the trial, designed to treat solid tumours, was dosed at City of Hope's NCI-Designated Comprehensive Cancer Center in Duarte, California, USA.

The first-in-class Phase 1 clinical trial of onCARlytics (on-CAR-19 CF33-CD19 HOV4), known as OASIS, is being conducted in patients with solid tumours and is titled "A Phase I Dose Escalation and Dose Expansion Safety and Tolerability Study of onCARlytics (CF33-



CD19) Administered Intravenously or Intratumorally in Combination with Blinatumomab in Adults with Advanced or Metastatic Solid Tumours”. The trial seeks to evaluate the safety and efficacy of two routes of administration – intratumoural (IT) injection and intravenous (IV) infusion – either alone or in combination with blinatumomab.

In combining with the CD19 targeting Blinatumomab (also known as Blincyto®), onCARlytics has the potential to target and eradicate solid tumours that cannot typically be treated with Blincyto® alone.

The dose escalation trial is being conducted across multiple US sites and is a world-first having a CD19 oncolytic virus combination with a CD19 directed therapeutic.

Azer-cel hits major milestone with the first patient dosed in the Phase 1b trial

In November, the Company announced the dosing of the first patient with the FDA cleared manufacturing process 1.2 in a Phase 1b clinical trial using its azer-cel technology, an allogeneic off-the-shelf CD19 CAR T cell therapy. The trial is being conducted in patients with non-Hodgkin’s lymphoma (NHL) and B-cell acute lymphocytic leukemia (ALL). This first patient, treated at Banner Health in Phoenix, Arizona, has Diffuse-Large B-cell lymphoma (DLBCL), a challenging subset of NHL.

The Phase 1b trial follows the successful completion of a Phase 1 study in 84 patients across leading US centres, demonstrating strong safety and efficacy signals from azer-cel. The Phase 1b trial aims to build on the promising results observed in DLBCL patients who relapsed following CAR T therapy. Azer-cel has shown clinically meaningful activity with an acceptable safety profile.

Imugene’s azer-cel clinical drug is supplied from the company’s state-of-the-art manufacturing facility in North Carolina. Following the Phase 1b study, there is potential to start a registrational study in 2024, with the aim of azer-cel becoming the first approved allogeneic CAR T cell therapy for cancer.



PD1-Vaxx Phase 2 neoPOLEM clinical trial to open in UK & Australia; European patent to be granted

In December, Imugene announced the commencement of a Phase 2 neoPOLEM clinical trial for PD1-Vaxx in patients with colorectal cancer (CRC) in the United Kingdom and Australia. This trial, set to begin in 2024, will evaluate the efficacy of PD1-Vaxx in combination with standard-of-care chemotherapy for CRC. Approximately 44 patients will be enrolled across approximately 10 sites – 6 in Australia and 4 in the UK.

The trial, is an Investigator Sponsored Study (IST) and will be conducted by Cancer Research UK Southampton Clinical Trials Unit in collaboration with Royal Surrey Hospital NHS Foundation Trust and The Australasian Gastro-Intestinal Trials Group (AGITG). The primary objective of the study is to determine major pathological response rates, a measure of tumour size reduction post-treatment with PD1-Vaxx before surgery.

The Company also announced it will be granted a patent in Europe for PD1-Vaxx. Corresponding applications are pending in Canada, China, Hong Kong, India, South Korea, Brazil and Australia. The patent has previously received a Notice of Grant in the US and Japan.

Strategic research collaboration with NeolmmuneTech

In December the Company announced a strategic collaboration with NeolmmuneTech (NIT) to enhance cancer treatments. This collaboration will focus on evaluating the potential of NIT's immune cell amplifier NT-17 to improve the efficacy of Imugene's azer-cel technology.

The partnership aims to explore:

- The ability of NIT's NT-17 to increase the number of azer-cel allogeneic CAR T cells per batch during manufacturing. This could potentially enhance the scalability and accessibility of this novel therapy.



- The potential for the combination to increase the number and cancer-fighting properties of patients' own T cells during treatment with azer-cel.

The collaboration is set to continue for two years, with research activities being conducted exclusively in the United States. Both parties retain intellectual property rights to their respective technologies, and any new intellectual property generated from this collaboration will be discussed for joint filing and prosecution.

Participation at JP Morgan Healthcare Conference

Imugene announced its participation at the 42nd Annual J.P. Morgan Healthcare Conference, which took place subsequent to the end of the reporting period. At the conference, CEO & MD Leslie Chong showcased Imugene's technology to a varied audience of industry participants and investors who travel from around the world for what is considered a key event on the biotechnology calendar.

The J.P. Morgan Healthcare Conference is renowned as one of the largest and most prestigious events in the sector. The 2023 event witnessed attendance from over 8,000 investors, senior industry professionals, and government officials. This marked the second consecutive year Imugene was invited to speak at the conference.

A replay of CEO & MD Leslie Chong's presentation is available at:

<https://www.youtube.com/watch?v=layFQEmilFM>

HER-Vaxx and CHECKVacc featured at ESMO Congress

In October, Imugene announced presentations of its B cell immunotherapy HER-Vaxx and CF33 oncolytic virotherapy CHECKVacc at the ESMO Congress in Madrid.



The European Society for Medical Oncology (ESMO) Congress is the most influential oncology platform for clinicians, researchers, patient advocates, journalists, and healthcare industry representatives from all over the world.

Imugene saw two poster presentations pertaining to HER-Vaxx with a third with regards to CHECKVacc. These are available to be viewed on the Imugene website:

<https://www.imugene.com/conference-presentations>

Non-Deal Roadshow Webinar

Imugene Managing Director and CEO Leslie Chong, Chief Operating Officer Dr Bradley Glover and Chief Medical Officer Dr Paul Woodard hosted an investor webinar in November as part of the Company's Non-Deal Roadshow. A replay is available at:

<https://www.youtube.com/watch?v=BoLoplUXRm8>

AGM

Imugene's Annual General Meeting (AGM) was held on 30 November 2023, at which all resolutions put forward to shareholders were passed by way of a poll.

Financials

At the end of the December quarter Imugene has **\$139.4 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 **\$24.2 million**, with direct research and development and staff costs accounting for 50% 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, performance rights and RSUs 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

99 009 179 551

Quarter ended ("current quarter")

31 December 2023

Consolidated 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	(12,137)	(26,792)
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs	(6,434)	(12,306)
(f) administration and corporate costs	(6,970)	(9,497)
1.3 Dividends received (see note 3)		
1.4 Interest received	1,367	2,452
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)		
1.9 Net cash from / (used in) operating activities	(24,175)	(46,144)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities		
(b) businesses		(18,142)
(c) property, plant and equipment		(4)
(d) investments		
(e) intellectual property		
(f) other non-current assets		

Consolidated 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		
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	(18,146)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	705	51,323
3.2	Proceeds from issue of convertible debt securities		
3.3	Proceeds from exercise of options		
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(525)	(573)
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	181	50,750

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	163,390	153,151
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(24,175)	(46,144)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	0	(18,146)

Consolidated 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)	181	50,750
4.5	Effect of movement in exchange rates on cash held	(4)	(219)
4.6	Cash and cash equivalents at end of period	139,392	139,392

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	90,002	114,185
5.2	Call deposits	49,389	49,205
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)	139,392	163,390

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	295
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.

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

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)	(24,175)
8.2 Cash and cash equivalents at quarter end (item 4.6)	139,392
8.3 Unused finance facilities available at quarter end (item 7.5)	
8.4 Total available funding (item 8.2 + item 8.3)	139,392
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	6
<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: ...31 January 2024.....

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.