



**IMUGENE**

Developing Cancer  
Immunotherapies

ASX: IMU

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

**Quarter Ended:  
30 June, 2023**

**Imugene Limited  
ABN 99 009 179 551**

[www.imugene.com](http://www.imugene.com)

## ASX Announcement

### Quarterly Activities and Cash Flow Report

**Quarter ended 30 June 2023**

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- FDA IND received to commence onCARlytics first-in-class study
- VAXINIA MAST trial continues progress through cohorts
- First combination patient dosed in PD1-Vaxx IMPRINTER study
- onCARlytics virus combined with ARTEMIS® T cells demonstrate enhanced anti-tumour activity in primary liver cancer
- Positive CHECKvacc imaging data presented at AACR
- HER-Vaxx induced antibodies correlated with tumour reduction
- PD1-Vaxx patent extended to 2040
- Prominent US biotech executive Kim Drapkin appointed Non-Executive Director
- \$12.6m R&D tax refund received

**SYDNEY, Australia, 21 July 2023:** 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 June 2023.

#### **FDA clears IND for Imugene to commence onCARlytics Phase 1 clinical trial**

During May, Imugene was pleased to announce it received US Food and Drug Administration (FDA) Investigational New Drug (IND) clearance to initiate a Phase 1 clinical study of its oncolytic virotherapy candidate, onCARlytics (on-CAR-19, CF33-CD19, HOV4).

The FDA clearance of the IND allows Imugene to start patient recruitment and dosing in a first-in-class Phase 1 clinical study for the onCARlytics platform in patients with solid tumours: “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 Tumors (OASIS).”



Imugene's CF33-CD19 oncolytic virus, when combined with the CD19 targeting bispecific monoclonal antibody blinatumomab (Blinicyto®), has the potential to target and eradicate solid tumours that otherwise cannot be treated with Blincyto® therapy alone.

Imugene Managing Director and CEO Leslie Chong, alongside Scientific Advisory Board member and onCARlytics co-inventor Dr Saul Priceman, held an investor webinar to discuss the FDA IND clearance. It can be viewed at: <https://youtu.be/bkcmDym8Qic>

### VAXINIA MAST trial continues positive momentum

Imugene's Phase 1 MAST (metastatic advanced solid tumours) trial evaluating the safety of novel cancer-killing virus CF33-hNIS (VAXINIA) has continued to progress on schedule.

#### Dose Administration (Parallel Groups)

n=52-100

IT

IT Administration  
Metastatic and Advanced  
Solid Tumors

IV

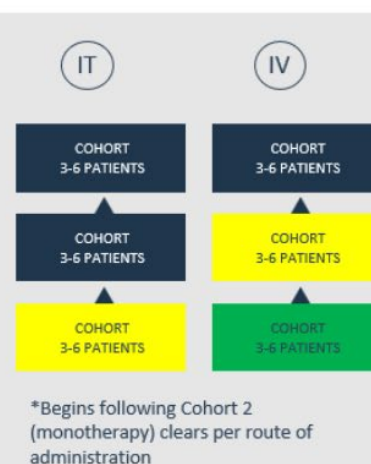
IV Administration  
Metastatic and Advanced  
Solid Tumors

Site Location: USA, AUS

#### VAXINIA Monotherapy Dose Escalation



#### VAXINIA + Pembrolizumab Combination Dose Escalation\*



The trial has now reached dosing for:

- The third cohort of the intratumoral (IT) arm of the monotherapy study
- The fourth and final cohort of the intravenous (IV) arm of the monotherapy study
- The first cohort of the IT arm of the combination study
- The second cohort of the IV arm of the combination study

The multicenter Phase 1 MAST trial commenced by delivering a low dose of VAXINIA to patients with metastatic or advanced solid tumours who have had at least two prior lines of standard of care treatment. The City of Hope-developed oncolytic virus has been shown to shrink colon, lung, breast, ovarian and pancreatic cancer tumours in preclinical



laboratory and animal models<sup>1</sup>. Overall, the study aims to recruit up to 100 patients across approximately 10 trial sites in the United States and Australia.

### **First patient dosed in combination study for PD1-Vaxx IMPRINTER clinical trial**

On 1 June the Company announced the first patient had been dosed in the combination cohort of the IMPRINTER study, a clinical trial to evaluate the safety and efficacy of Imugene's PD1- Vaxx, a B-cell activating immunotherapy alone or in combination with atezolizumab (Tecentriq®), an immune checkpoint inhibitor targeting PD-L1 from Roche, in patients with non-small cell lung cancer (NSCLC).

The objectives of the open label, multi-center, dose escalation/expansion, phase 1/1b study of IMU-201 (PD1-Vaxx), a B-Cell Immunotherapy as monotherapy or in combination with atezolizumab with or without chemotherapy, in adults with non-small cell lung cancer (IMPRINTER), are to determine safety, efficacy, and optimal dose of PD1-Vaxx in combination with atezolizumab as therapy in ICI treatment-naïve NSCLC patients or ICI pretreated patients.

The study is being conducted at sites in USA and Australia. Dual targeting of the PD-1/PD-L1 axis is an area of considerable interest, providing treatment options for patients with cancer. Combination with PD1-Vaxx may overcome treatment resistance to ICIs with dual inhibition of the PD-1/PD-L1 axis extending the treatment benefit of atezolizumab. In contrast to the combination of two monoclonal antibodies, PD1-Vaxx induces a unique polyclonal immune response which may increase response rates for the combination therapy.

### **Positive new data for onCARlytics virus combined with ARTEMIS® T cells**

In May Imugene's onCARlytics technology, in combination with Eureka Therapeutics, Inc.'s ARTEMIS® cell receptor platform, had preclinical data presented at the American Society of Gene and Cell Therapy's Annual Meeting (ASGCT). The data demonstrated enhanced anti-tumour activity in vivo against hepatocellular carcinoma (liver cancer) tumours.

Presented as a poster presentation at the ASGCT conference held in Los Angeles, titled 'Effective combination immunotherapy using onCARlytics and ARTEMIS® CD19 T cells against hepatocellular carcinoma', the data investigated the combination in the most common type of primary liver cancer and sixth most common cancer worldwide.



Hepatocellular carcinoma (HCC) occurs most often in people with chronic liver diseases, such as cirrhosis caused by hepatitis B or hepatitis C infection.

Currently, there are few systemic therapies available for patients with advanced disease in addition to the traditional treatments including ablation, surgical resection, and liver transplantation. CD19-targeting chimeric antigen receptor (CAR) T cell therapy has demonstrated impressive clinical outcomes in blood cancers, but translating this therapy to solid-tumour cancers has met various challenges, including the immunosuppressive microenvironment, on-target off-tumour toxicity, and antigen heterogeneity. To date, CAR T cell therapies against HCC have shown nominal efficacy in clinical trials. Therefore, development of novel and innovative therapeutic approaches against HCC is needed to overcome the challenges and improve clinical outcomes.

onCARlytics in combination with ARTEMIS® T cells potentially provide a solution. ARTEMIS® T cells differentiate from CAR T cells with lower CRS risks, better tumour infiltration, and higher T cell persistence in pre-clinical studies, making them ideal cell therapy candidates for solid tumours.

The ASGCT event is now in its 26th year and attracts a range of professionals in the area of gene and cell therapy, who observe new scientific research and technologies alongside peers in the industry. It is being held 16-20 May 2023 at the Los Angeles Convention Center, CA, USA.

The poster presentation can be viewed on the Imugene website, <https://www.imugene.com/conference-presentations>.

### **Positive imaging data presented on CHECKvacc**

At the AACR Annual Meeting held in Orlando, Florida during April, Imugene presented positive imaging data on its oncolytic virotherapy candidate, CHECKvacc (CF33-hNIS-antiPDL1).

Dr. Jamie Rand, an Assistant Professor in the Division of Breast Surgery at the City of Hope's Department of Surgery, presented the abstract titled "hNIS imaging data from a first-in-human trial of the oncolytic virus CF33-hNIS-antiPD-L1 in patients with triple negative breast cancer".



The conclusions of the abstract were as follows:

- CF33-hNIS-antiPD-L1 is safe and well tolerated at dose levels 1 through 3.
- SPECT (single-photon emission computerized tomography) imaging after treatment with CF33-hNIS-antiPD-L1 administered by IT (intratumoral) injection in patients with mTNBC (metastatic triple-negative breast cancer) showed enhancement in 75% of injected lesions, suggesting local viral replication with resulting hNIS (human sodium iodide symporter) expression.
- This technique allows Imugene to track where the virus is replicating in real time during treatment.
- This is the first known report of successful hNIS-based imaging to track oncolytic poxvirus replication in humans.
- There was improved SPECT imaging enhancement in subcutaneous nodules, intramuscular nodules, and lymph nodes when compared to matted dermal metastasis.
- Further analysis will evaluate the correlation of SPECT imaging results with pathologic immune cell infiltrate, viral staining, and tumor response. Preliminary evaluation suggests increased CD8+ T-cell infiltration and increased PD-L1 expression following IT injection of CF33-hNIS-antiPD-L1.

The poster is available on Imugene's website: <https://www.imugene.com/conference-presentations>

### **HER-Vaxx induced antibodies correlated with tumour reduction**

At the end of the period Imugene announced new HER-Vaxx data was presented at the World Congress of Gastrointestinal Cancer in Barcelona.

For 25 years, the World Congress on Gastrointestinal Cancer has been the foundation for sharing the most advanced research and innovations impacting the field of Gastrointestinal Cancer. As the largest global gathering in the field, the Congress brings together leading gastroenterology, oncology, pathology, and hepatology experts, clinicians, and surgeons, as well as clinical researchers from across the globe to share pioneering research, approaches, and best practices in treating patients with cancers of the gastrointestinal tract.

Conclusions drawn from Imugene's HERIZON study, presented at the congress, included:

- HER-Vaxx treatment produced robust anti-HER-2-IgG\* and IgG1 antibody responses ( $p < 0.001$ ).





- HER-Vaxx-based vaccination of patients with HER-2 overexpressing gastric/gastro-esophageal junction cancer (GC) induced anti-HER-2-IgG and IgG1 subclass antibody responses ( $p < 0.001$ ).
- HER-Vaxx induced antibodies correlated with tumour reduction ( $p = 0.001$ ).
- Compared to chemotherapy alone, the vaccination resulted in a statistically significant overall survival benefit.
- The present data further validate the proof of concept for a first-in-class B-cell immunotherapy based on HER-2/neu peptides.

\* IgG - Immunoglobulin G is a type of antibody. Representing approximately 75% of serum antibodies in humans, IgG is the most common type of antibody found in blood circulation.

### **Extension of PD1-Vaxx US patent**

Imugene announced the grant of a new patent (number 11,684,929) by the United States Patent Office during June.

The granted claims protect Imugene's immunotherapeutic PD1-Vaxx, a first-in-class programmed death-1 (PD1) vaccine, currently in clinical development for non-small cell lung cancer (NSCLC).

The patent titled "HUMAN PD1 PEPTIDE VACCINES AND USES THEREOF" will expire on 11 February 2040 (including 685 days of patent term adjustment added to the original expiry date of 28 March 2038) and protects the composition of matter and method of treatment in cancer of Imugene's PD1-Vaxx for the generation of a therapeutic antibody response against the PD1 checkpoint target.

### **Ms Kim Drapkin appointed to the Imugene board**

The Company announced it had appointed prominent US biotech executive Ms Kim Drapkin as a Non-Executive Director during the period.

With more than 25 years of experience in the biotechnology and pharmaceutical sectors, Ms Drapkin possesses a strong background in finance, capital raising, and strategic financial planning. She held the position of CFO and Treasurer at Jounce Therapeutics, Inc. from 2015 until its acquisition in May 2023, having played a pivotal role in the company's growth and financing since its inception. Alongside the CEO, she represented Jounce in the investment and analyst community and was a key figure in the company's IPO and subsequent NASDAQ listing.



Before joining Jounce, Ms Drapkin managed a financial consulting firm and served as interim CFO for various early-stage biotech companies, including Eleven Biotherapeutics, Inc., NinePoint Medical, Inc., Blueprint Medicines Corporation, Warp Drive Bio LLC, Edimer Pharmaceuticals, Avila Therapeutics, Inc., and Voyager Therapeutics, Inc. Prior to that, she held CFO positions at EPIX Pharmaceuticals and gained valuable experience at Millennium Pharmaceuticals.

Ms Drapkin also currently serves as the audit committee chair and compensation committee member on Acumen Pharmaceuticals' board (NASDAQ: ABOS). Previously, she served on Proteostasis Therapeutics' board (NASDAQ: PTI) from 2019 to 2020 and continued on Yumanity Therapeutics' board (NASDAQ: YMTX) following its merger with PTI in December 2020 until December 2022. In PTI and Yumanity, she chaired the audit committee and participated in the governance and compensation committees. Ms. Drapkin also served on transaction committees for both companies.

Concurrently with Ms Drapkin's appointment, Imugene announced that Charles Walker resigned from his position as a Non-Executive Director of the Company. Charles served on Imugene's Board since August 2014, including a tenure as CEO, and provided a valued contribution and wise counsel to the Company.

## Financials

At the end of the June quarter Imugene has **\$153.2 million** in cash or equivalents, providing a runway to support its clinical pipeline and operations. Net cash received in operating activities for the quarter amounted to **\$1.59 million**, with direct research and development and staff costs accounting for **76%** of total costs. During the period Imugene received its research and development (R&D) tax refund for the 2022 financial year, totalling \$12.6m. The refund is received as part of the Australian Government's R&D tax incentive, which provides companies engaging in appropriate and eligible activities with a refundable tax offset of up to 43.5%. The refund received by Imugene will enable the further clinical development of its immuno-oncology pipeline.

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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<sup>1</sup> Warner SG, Kim SI, Chaurasiya S, O'Leary MP, Lu J, Sivanandam V, Woo Y, Chen NG, Fong Y. A Novel Chimeric Poxvirus Encoding hNIS Is Tumor-Tropic, Imageable, and Synergistic with Radioiodine to Sustain Colon Cancer Regression. *Mol Ther Oncolytics*. 2019 Apr 11;13:82-92. doi: 10.1016/j.omto.2019.04.001. PMID: 31061881; PMCID: PMC6495072.

## 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 product pipeline 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*

## 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")**

30 June 2023

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(9,154)	(30,557)
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs	(1,933)	(7,913)
(f) administration and corporate costs	(989)	(5,986)
1.3 Dividends received (see note 3)		
1.4 Interest received	800	1589
1.5 Interest and other costs of finance paid		
1.6 Income taxes paid		
1.7 Government grants and tax incentives	12,717	12,717
1.8 Other (provide details if material)	143	866
<b>1.9 Net cash from / (used in) operating activities</b>	<b>1,585</b>	<b>(29,283)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities		
(b) businesses		
(c) property, plant and equipment		(5)
(d) investments		
(e) intellectual property		
(f) other non-current assets		

Consolidated 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		
	(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)		
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>0</b>	<b>(5)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)		80,000
3.2	Proceeds from issue of convertible debt securities		
3.3	Proceeds from exercise of options		8,417
3.4	Transaction costs related to issues of equity securities or convertible debt securities		(5,402)
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)		
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>0</b>	<b>83,015</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	151,457	99,888
4.2	Net cash from / (used in) operating activities (item 1.9 above)	1,585	(29,283)
4.3	Net cash from / (used in) investing activities (item 2.6 above)		(5)

Consolidated 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)	0	83,015
4.5	Effect of movement in exchange rates on cash held	109	(464)
4.6	<b>Cash and cash equivalents at end of period</b>	<b>153,151</b>	<b>153,151</b>

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	103,980	122,379
5.2	Call deposits	49,170	29,078
5.3	Bank overdrafts		
5.4	Other (provide details)		
5.5	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>153,151</b>	<b>151,457</b>

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	836
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>		

<b>7.</b>	<b>Financing facilities</b> <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
7.1	Loan facilities		
7.2	Credit standby arrangements		
7.3	Other (please specify)		
7.4	<b>Total financing facilities</b>		
7.5	<b>Unused financing facilities available at quarter end</b>		
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.		

<b>8.</b>	<b>Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1	Net cash from / (used in) operating activities (item 1.9)	1,585
8.2	Cash and cash equivalents at quarter end (item 4.6)	153,151
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	<b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	N/A
	<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: 21 July 2023

Authorised by: By the board  
(Name of body or officer authorising release – see note 4)

### 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.