

For personal use only

# Quarterly Activities & Cash Report and 4C

For the quarter ended  
**31 March 2022**



**IMUGENE**

ABN 99 009 179 551

**ASX Announcement****Quarterly Activities and Cash Flow Report  
Quarter ended 31 March 2022**

**SYDNEY, Australia, 22 April 2022:** 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 2022.

Key highlights this quarter included:

- **Clinical trial supply agreement to evaluate PD1-Vaxx in combination with atezolizumab (Tecentriq®) for patients with non-small cell lung cancer**
- **Clinical trial supply agreement to evaluate HER-Vaxx in combination with pembrolizumab (KEYTRUDA®) for treatment of HER 2 positive gastric cancer**
- **Phase I clinical trial of CHECKvacc for triple negative breast cancer will proceed to the second dose cohort**
- **PD1 Vaxx has completed its Phase 1a monotherapy dose escalation and will proceed to combination dose escalation after review by Cohort Review Committee (CRC)**
- **Western Institutional Review Board (WIRB) approval to commence a Phase I clinical trial of VAXINIA in multiple solid tumours in patients**
- **Notice of Grants received from South Korean Intellectual Property Office and European Patent Office for patent applications protecting its HER Vaxx immunotherapy**
- **Notice of Grant received from Japanese Patent Office patent application for CF33, including VAXINIA and CHECKVacc**
- **Ursula McCurry and Dr Nimali Withana appointed as Senior Vice President of Clinical Operations and Senior Director of Clinical Science respectively**
- **\$109.1m cash balance as at 31 March 2022**
- **Quarterly research and development expenditure was \$8.2m**

**PD1-Vaxx clinical trial supply agreement**

During January Imugene announced it has signed a new clinical trial supply agreement to evaluate the safety and efficacy of Imugene's PD1-Vaxx in combination with atezolizumab (Tecentriq®) in patients with non-small cell lung cancer (NSCLC).

The objectives of the phase 1b trial are to determine safety, efficacy, and optimal dose of PD1-Vaxx in combination with atezolizumab as either first-line therapy in ICI treatment-naïve NSCLC patients or ICI pre-treated patients. The study will be conducted at sites in USA and Australia.

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.

Tecentriq has previously shown clinically meaningful benefit in various types of lung cancer, with six currently approved indications in the US. In addition to becoming the first approved cancer immunotherapy for adjuvant NSCLC, Tecentriq was also the first approved cancer immunotherapy for front-line treatment of adults with extensive-stage small cell lung cancer (SCLC) in combination with carboplatin and etoposide (chemotherapy). Tecentriq also has four approved indications in

advanced NSCLC as either a single agent or in combination with targeted therapies and/or chemotherapies.

The supply agreement is for a period of up to five years for the supply of atezolizumab. Imugene will be the sponsor of the study and will fund the clinical study from existing budgets and resources. Atezolizumab will be supplied for the duration of the study.

#### **HER-Vaxx clinical trial supply agreement**

Imugene announced during March it had entered into a new clinical trial supply agreement to evaluate the safety and efficacy of Imugene's HER-Vaxx, a B-cell activating immunotherapy, in combination with anti-PD-1 therapy, pembrolizumab (KEYTRUDA®), in patients with HER-2 positive gastric cancer.

The study, to be known as nextHERIZON is an open-label, multi-center, signal generating, Phase 2 clinical trial designed to assess the safety and efficacy of HER-Vaxx in combination with chemotherapy or pembrolizumab in patients with metastatic HER-2/neu over-expressing gastric or gastroesophageal junction adenocarcinomas who have previously progressed on trastuzumab. The study's primary endpoints are safety and response rate. Secondary endpoints include duration of response, progression free survival, overall survival, and biomarker evaluation.

Under the agreement, Imugene will be the sponsor of the study and will fund the clinical study from existing budgets and resources. Pembrolizumab will be supplied for the duration of the study. The agreement is for an indefinite term until final reports of the study have been completed, noting that the underlying study is anticipated to run for at least 24 months. The agreement includes customary termination and intellectual property provisions for a clinical collaboration agreement.

#### **CHECKVacc clinical trial phase 1 dose escalation**

During March, City of Hope®, a world-renowned independent cancer research and treatment center near Los Angeles, confirmed the Phase I clinical trial of its oncolytic virotherapy candidate, CHECKvacc (HOV3, CF33-hNIS-anti-PDL1), will proceed to the second dose cohort.

The Protocol Management Team found CHECKvacc to be safe with no dose-limiting toxicities (DLTs) and no serious adverse reactions observed after review of all safety and tolerability data for the first 3 patients dosed with lowest dose of CHECKvacc as monotherapy. City of Hope® will proceed with opening the second CHECKvacc Phase 1 cohort.

The first-in-human, Phase 1, single-centre, dose escalation study of CHECKvacc is recruiting patients with triple negative breast cancer (TNBC). The purpose of the study is to evaluate the safety and initial evidence of efficacy of intra-tumoural administration of CF33-hNIS-antiPDL1 against metastatic TNBC. The current trial design will involve a dose escalation, followed by an expansion to 12 patients at the final dose, which will be the recommended phase 2 dose (RP2D). The trial is anticipated to run for 24 months and is funded from existing budgets and resources.

#### **PD1-Vaxx completes Phase 1a monotherapy dose escalation**

In January, Imugene announced the Cohort Review Committee (CRC) had confirmed its checkpoint immunotherapy candidate, PD1-Vaxx, had completed its Phase 1a monotherapy dose escalation and will proceed to combination dose escalation.

The Phase 1a monotherapy dose escalation was performed with 10, 50 and 100µg of PD1-Vaxx in non-small cell lung cancer (NSCLC) patients who progressed on one or more immune checkpoint inhibitors (ICIs).

After CRC review of monotherapy safety, tolerability and biomarker data, it advised Imugene to proceed to the combination phase of clinical development of PD1-Vaxx.

The primary objective of the phase 1 trial is to determine safety and optimal biological dose as monotherapy and in combination with immune checkpoint inhibitors (ICI). As mentioned above, plans are now being finalized to combine PD1-Vaxx with PD-L1 targeting blockbuster ICI atezolizumab (Tecentriq) as first-line in ICI treatment naïve NSCLC patients.

Dual targeting of the PD-1/PD-L1 axis is an area of considerable interest with ongoing clinical results creating strong interest inside the pharma industry. 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 combination of two monoclonal antibodies, PD1-Vaxx has the advantage that it induces a unique polyclonal immune response which may increase response rates for the combination therapy.

#### **VAXINIA receives approval to start phase 1 clinical trial**

Imugene received Western Institutional Review Board (WIRB) approval to commence a Phase I clinical trial of its oncolytic virotherapy candidate, VAXINIA (CF33-hNIS, HOV2) in multiple solid tumours in patients.

The US component of the Phase I trial will be conducted under the Food and Drug Administration (FDA) investigational new drug (IND) process following FDA IND clearance in December 2021. Site activation and patient recruitment commenced immediately after the approval was received. The first hospital in the USA to receive ethics approval is independent cancer research and treatment center City of Hope®. Additional clinical sites will be opened across the USA in 2022.

The trial is anticipated to run for 24 months and will be led by Principal Investigator at City of Hope®, Dr Daneng Li MD, an assistant professor in the Department of Medical Oncology & Therapeutics Research at City of Hope, specializing in treating gastrointestinal cancers. Dr Li currently leads the liver tumours program and is also the co-director of the Neuroendocrine Tumour Program at City of Hope.

This is an open-label, dose-escalation, multi-centre phase I study evaluating the safety of CF33-hNIS (hNIS – human sodium iodide symporter) administered via two routes of administration, intratumoural (IT) or intravenous (IV), either as a monotherapy or in combination with pembrolizumab administered intravenously in patients with metastatic or advanced solid tumours.

The trial will involve a dose escalation before the trial expands to up to 10 patients at the final monotherapy and combination dose.

#### **HER-Vaxx patent granted in South Korea and Europe**

In January, Imugene announced it had received Notice of Grants from both the South Korean Intellectual Property Office and European Patent Office for patent applications protecting its HER Vaxx immunotherapy, currently in development for HER-2 positive gastric cancer.

The patent titled “A VACCINE COMPOSITION AND USES THEREOF” protects the method of composition and method of use of Imugene’s HER-Vaxx immunotherapy to 2036.

Importantly, South Korea is a selected country to conduct the nextHERIZON Phase 2 clinical trial in 2022 and has one of the highest incidence rates of gastric cancer worldwide, with approximately one in five cases considered HER2 positive. This is an open-label, signal generating, phase 2 study of HER Vaxx in combination with chemotherapy or pembrolizumab in patients with metastatic HER2/neu over-expressing gastric or gastroesophageal junction (GEJ) adenocarcinomas who have previously received trastuzumab and progressed on this treatment.

Attaining the key European patent is also a significant milestone and is another major pharmaceutical market to grant patent protection for HER-Vaxx.

### **Oncolytic Virotherapy CF33 Patent Granted in Japan**

Imugene received a Notice of Grant from the Japanese Patent Office for the patent application which protects its oncolytic virotherapy CF33, including VAXINIA (CF33-hNIS) and CHECKVacc (CF33-hNIS-antiPDL1).

The patent titled “CHIMERIC POXVIRUS COMPOSITION AND USES THEREOF” (inventors Yuman Fong and Nanhai Chen from the City of Hope®) protects the method of composition and method of use of Imugene’s licensed oncolytic virotherapy to 2037.

CF33 is a chimeric vaccinia poxvirus from the lab of inventor Professor Yuman Fong, Chair of Sangiacomo Family Chair in Surgical Oncology at City of Hope®, and a noted expert in the oncolytic virus field.

Oncolytic viruses (OVs) are designed to both selectively kill tumour cells and activate the immune system against cancer cells, with the potential to improve clinical response and survival.

### **Financial Update**

At the end of the period Imugene has \$109.1 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 \$10.8 million, with direct Research and Development amounting to \$8.2 million and with Staff costs accounting for over 90% of the \$10.8 million for the quarter.

Imugene also successfully raised \$1.55 million through the exercise of options during the quarter. The funds will be used to support the Company’s commercial and clinical milestones.

The Company continues to monitor its expenditure carefully across all facets of the business, though this is expected to increase as clinical programs ramp up.

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.

## Industry leaders added to Senior Management Team

In January, Imugene appointed former Roche/Genentech employees and experts in oncology clinical development, Ursula McCurry and Dr Nimali Withana to its senior management team.

Ursula McCurry was appointed as the Senior Vice President of Clinical Operations. Ursula is a seasoned clinical operations leader with over 20 years of global clinical development experience across a number of established and emerging biotech and pharmaceutical companies including Genentech, Exelixis, Astex, QLT Inc and Amunix. She has led global clinical operations programs spanning a variety of therapeutic areas and all phases of clinical development, contributing to over 20 programs and subsequent multiple regulatory approvals at both small and large biotech companies. She also brings significant partnership and alliance management experience. Prior to joining Imugene, Ursula served as the VP of Clinical Operations at Amunix Pharmaceuticals and prior to that was a Clinical Program Director at Genentech, leading multiple programs from entry into the clinic to phase three development, including taselisib and GDC-9545. She has also led the Drug Safety teams, ensuring quality, compliance, pharmacovigilance, and safety reporting.

Ursula received a Master of Arts degree from Simon Fraser University and a certificate in Biotechnology, Clinical Trial Design and Management from San Francisco State University.

Dr Nimali Withana was appointed Senior Director of Clinical Science and has over 18 years of drug development experience spanning both academia and industry. Most recently she was the Lead Country Medical Manager for the Breast Cancer and Cancer Immunotherapy portfolios including bevacizumab, trastuzumab emtansine, ipatasertib and atezolizumab at Hoffman-La Roche New Zealand. Prior to that, she was the Clinical Scientist Lead across Phase I – III global oncology trials at Genentech.

Dr Withana received her academic training at Stanford University and The Peter MacCallum Cancer Centre, majoring in Immunology and Molecular Medicine. She has an in-depth understanding and grasp of the development process with experience in R&D, Clinical Trials and Patient Advocacy.

For more information please contact:

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

**Investor Enquires**  
investor@imugene.com

**Media Enquires**  
Matt Wright  
matt@nwrcommunications.com.au

Follow us on Twitter @TeamImugene  
Like us on Facebook @Imugene  
Connect with us on LinkedIn @Imugene Limited

## **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*

*Imugene Limited, Level 3, 62 Lygon Street, Carlton, VIC, 3053, Australia*

## 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 2022

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (9 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	(8,223)	(20,430)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(1,611)	(3,829)
(f) administration and corporate costs	(1,179)	(3,969)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	26	151
1.5 Interest and other costs of finance paid	(1)	(1)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	6,542
1.8 Other (provide details if material)	150	778
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(10,838)</b>	<b>(20,758)</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 (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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</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)	-	95,000
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	1,557	13,119
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(11)	(6,581)
3.5	Proceeds from borrowings	92	134
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other – repayment of debt	-	(1,361)
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>1,638</b>	<b>100,311</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	118,406	29,487
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(10,838)	(20,758)
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 (9 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1,638	100,311
4.5	Effect of movement in exchange rates on cash held	(79)	92
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>109,127</b>	<b>109,127</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	59,117	68,401
5.2	Call deposits	50,010	50,005
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>109,127</b>	<b>118,406</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	303
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.

7. <b>Financing facilities</b> <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>	<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.	N/A	

8. <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)	(10,838)
8.2 Cash and cash equivalents at quarter end (item 4.6)	109,127
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	109,127
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	10.1
<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: 22 April 2022

Authorised 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.



For personal use only

Quarterly Activities &  
Cash Report and 4C  
For the quarter ended  
31 March 2022



**IMUGENE**