IMUGENE

Developing Cancer Immunotherapies

ASX: IMU



# QUARTERLY ACTIVITIES & APPENDIX 4C CASH REPORT

## Quarter Ended: 30 September, 2023

**Imugene Limited**
**ABN 99 009 179 551**

**www.imugene.com**

IMUGENE
Developing Cancer Immunotherapies

## ASX Announcement

# Quarterly Activities and Cash Flow Report

# Quarter ended 30 September 2023

- **Global license acquired for azer-cel allogeneic CD19 CAR T cell therapy**
  **- Positive feedback from FDA on improved manufacturing process**
  **- FDA IND transferred to Imugene**
- **Phase 1 MAST trial for VAXINIA (CF33- hNIS) continues advancement through dose escalation cohorts**
- **Collaboration with RenovoRx commenced to enhance oncolytic virus therapy delivery to hard to treat cancers such as pancreatic**
- **Japanese patent secured for PD1-Vaxx drug candidate**
- **Imugene's technologies to again be showcased at SITC, ESMO**
- **Several key management appointments including new COO, CMO and SVP Clinical Development**
- **Placement and SPP activities generate a total of $53.2m in new capital raised**

**SYDNEY, Australia, 31 October 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 September 2023.

### Acquisition of Azer-cel

In August 2023, Imugene secured a global exclusive license for Precision Biosciences, Inc.'s azer-cel allogeneic CD19 CAR T cell therapy program, an asset with an extensive clinical data set and fast-to-market development potential.

In an ongoing multi-centre Phase 1b clinical trial that includes 84 patients with non-Hodgkin's lymphoma (NHL) and acute lymphocytic leukemia (ALL), azer-cel has demonstrated clinically meaningful activity with an acceptable safety profile. Notably, the

azer-cel data were especially strong in patients with Diffuse Large B Cell Lymphoma (DLBCL) who had relapsed following auto CAR T therapy. Azer-cel achieved 83% Overall Response Rate (ORR), 61% Complete Response (CR) Rate with 55% durable response greater than or equal to six months in this difficult to treat auto CAR T relapse setting (n=18). It is estimated that 60-70% of patients treated with an approved auto CD19 CAR T cell therapy such as Kymriah®, Yescarta® or Breyanzi® will unfortunately have cancer progression or recurrence.

A positive meeting was held with the FDA in June 2023 to seek guidance for entering a Phase 2 registration study. Further, chemistry, manufacturing, and controls (CMC) discussions have gone well with the FDA and the intended commercial azer-cel product will be tested in the clinic and will be utilized in the potential registrational clinical trial.

As per the licensing agreement, Imugene will provide Precision Biosciences with a series of financial commitments, including an upfront cash payment, deferred considerations, and numerous potential milestone payments.

Additionally, Imugene will assume the lease of a GMP manufacturing facility in North Carolina and integrate a team of approximately 50 cell therapy and manufacturing experts. All financial commitments associated with this agreement will be funded through Imugene's cash reserves, with an option to make some payments in equity.

Following Imugene's acquisition of the asset, the FDA provided positive feedback on the azer-cel manufacturing process to be used in the pivotal clinical trial and potentially for manufacturing of the commercial product. Later in the reporting period the FDA also approved the transfer of the Investigational New Drug Application (IND) for azer-cel from Precision Biosciences to Imugene.

At the time of the acquisition of azer-cel, Imugene's Managing Director and CEO Leslie Chong hosted an investor webinar with COO Dr Bradley Glover. Watch the replay at: at: https://us02web.zoom.us/webinar/register/WN_5Pi9U92DTJCCLrmKacl9BQ.

The addition of azer-cel to our portfolio complements our existing assets exceptionally well. After careful consideration, we have decided that this acquisition fulfills our strategic objectives, and as a result, we will no longer seek further acquisitions at this time. We are confident that this move will strengthen our position in the market and enhance value for our stakeholders.

**VAXINIA trial clears Cohort 3 of IT monotherapy and Cohort 1 of IT combination**

In August, Imugene completed cohort 3 of the intratumoral arm of the monotherapy dose escalation study in its Phase 1 MAST trial for VAXINIA (CF33- hNIS), a cancer-fighting virus. The MAST trial began by providing patients with metastatic or advanced solid tumours with a low dose of VAXINIA after undergoing at least two prior lines of standard treatment. The oncolytic virus, developed by the City of Hope, can reduce various tumours in preclinical laboratory and animal tests. The study seeks to involve up to 100 patients from approximately ten trial sites in the US and Australia.

Later in the period, Imugene announced it had cleared cohort 1 of the intratumoral arm of the combination study with VAXINIA and Pembrolizumab, allowing for the initiation of recruitment for cohort 2 for both the intratumoral and intravenous arms in the combination study alongside cohort 4 in the monotherapy dose escalation. Like the monotherapy trial, the combination study involves metastatic or advanced solid tumour patients. The trial will run for around 24 months and is funded by cash reserves.

**CHECKvacc**

The trial is focused on recruiting patients with triple-negative breast cancer (TNBC) and is aimed to assess the safety of intra-tumoral administration of CF33-hNIS-antiPDL1 for metastatic TNBC.

After completion of the current cohort 4, the data derived from this trial will be used to inform our other CF33 clinical developments, and resources and finances from this study will be re directed to our priority programs,

**RenovoRx CF33 virotherapy delivery collaboration**

Early in the quarter, Imugene and RenovoRx, Inc. (Nasdaq: RNXT), a biopharmaceutical company specializing in targeted combination therapies, announced a strategic research collaboration aiming to enhance the delivery of Imugene's oncolytic virus therapy using RenovoRx's TAMP (Trans-Arterial Micro-Perfusion) therapy platform for treating difficult-to-access tumours.

The collaboration is set to explore the potential benefits of administering Imugene's CF33 oncolytic virus with RenovoRx's TAMP platform for tumours such as pancreatic and liver cancers. Traditional methods may be limited by dense fibrous tissue and inadequate blood supply to these tumours.

RenovoRx's TAMP platform, which won the Drug Delivery Technology category at the Fierce Innovation Awards – Life Sciences Edition 2020, has shown the potential to increase therapy efficacy by ensuring targeted delivery. A study indicated TAMP could achieve a 100-fold increase in local tissue concentration compared to conventional IV delivery.

The oncolytic virus patent covering VAXINIA (CF33-hNIS) and CHECKVacc (CF33-hNIS-antiPDL1) has been refiled with the USPTO for re-examination to strategically secure broader protection.

**PD1-Vaxx update**

In September, the Company announced that the Japanese Patent Office had granted its PD1-Vaxx clinical drug candidate a new patent (2019-553504). PD1-Vaxx is under clinical development for non-small cell lung cancer (NSCLC). Titled "HUMAN PD1 PEPTIDE VACCINES AND USES THEREOF", the patent will last until 28 March 2038 and covers the composition and treatment method in cancer for generating a therapeutic antibody response against the PD1 checkpoint target.

The OSU license covering non-PD1-Vaxx vaccines (e.g. B-Vaxx) has been returned to OSU for strategic reasons mainly due to lack of clinical development of the B-Vaxx HER2 vaccine.

**CF33 to be featured at SITC**

Imugene's CF33 Oncolytic Virus technology will be highlighted at the Annual Meeting for the Society for Immunotherapy of Cancer (SITC) in San Diego, USA, from 1-5 November 2023. SITC 2023 is a prestigious event showcasing advanced research presentations in immunotherapy. The CF33 technology will be presented through a Trial-in-Progress Poster: A Phase I Safety and Tolerability Study of VAXINIA (CF33-hNIS) in Adults with Metastatic or Advanced Solid Tumors. The abstract number is 730.

**HER-Vaxx and CHECKvacc to be featured at ESMO**

At the recently concluded ESMO Congress in Madrid, which took place from 20-24 October 2023, Imugene highlighted its B cell immunotherapy HER-Vaxx and CF33 oncolytic virotherapy CHECKVacc. The European Society for Medical Oncology (ESMO) Congress is a globally recognized platform in oncology, attracting professionals from various sectors.

At the congress, Imugene was featured in three poster sessions:

1. Poster #4720, titled "HERIZON: A Phase 2 study of HER-Vaxx (IMU-131), a HER2-targeting peptide vaccine plus standard of care chemotherapy in patients with

HER2+ advanced stomach Cancer", highlighted the correlation between dose-dependent anti-cancer antibodies and improved clinical outcomes. Dr. Joshua Tobias led the presentation from the Medical University of Vienna.

2. Poster 472P: Prevention of metastasis formation by combination therapy targeting Her2 and PD-L1 in Her2-expressing tumors based on observed efficacious vaccination against Her2-positive tumors. Presenter: Dr Joshua Tobias, Medical University of Vienna.
3. Poster #4581, titled "Induction of an Inflammatory Tumor Microenvironment with Oncolytic Virus CF33-hNIS-antiPD-L1 Intratumoral Injection in Patients with Metastatic Triple Negative Breast Cancer (mTNBC)", was presented by Dr. Jamie Rand from City of Hope.

All programs are presently undergoing evaluation as part of our program prioritization process. We are carefully assessing each clinical trial to align our efforts with our strategic objectives.

**Key Management Appointments:**

**Dr Bradley Glover appointed COO**

In August, Imugene announced the appointment of Dr Bradley Glover as its Chief Operating Officer. Dr Glover has extensive experience across various fields, including cell therapy, biopharmaceuticals, and diagnostics. He has a proven track record in strategic collaborations, acquisitions, licensing, and meaningful academic contributions in biochemistry and genetics.

Before joining Imugene, Dr Glover was the Executive Vice President and Chief Operating Officer at Celularity, where he had significant roles in strategic planning and business development. He also served as Vice President and Head of Corporate Strategy & operations at Kite Pharma, focusing on global corporate strategy and business

transformation. Dr Glover spent eight years at Genentech / Roche in leadership roles, primarily in business development and strategic planning, and played a crucial role in integrating Roche's acquisitions for its Diagnostics Sequencing business, amounting to approximately $1.2B.

**Dr Paul Woodard appointed Chief Medical Officer**

Dr Paul Woodard joined Imugene as Chief Medical Officer during the quarter. Before joining Imugene, Dr Woodard held roles in various drug development projects concerning solid tumours, hematologic malignancies, and non-malignant hematologic disorders. He was previously the Senior Vice President and Chief Medical Officer at Immune-Onc Therapeutics, where he was instrumental in clinical oversight, initiating Phase 1 clinical trials, and submitting four novel INDs.

Dr Woodard has also worked at Exelixis on tyrosine kinase inhibitors for solid tumours and played significant roles at Amgen, Genentech, and Bellicum. At Amgen, he led the global development of Nplate® for immune thrombocytopenia and myelodysplastic syndromes. At Genentech, he contributed to the developing of Tecentriq® in haematologic malignancies and its combinations in solid tumours. At Bellicum, he supervised the Company's cellular therapy portfolio and clinical trials.

**Dr John Byon appointed Senior Vice President of Clinical Development**

Imugene also announced the appointment of Dr John Byon as Senior Vice President of Clinical Development during the quarter. Dr Byon has a distinguished history in developing novel therapeutics for cancer patients, holding leadership roles in major biopharmaceutical companies.

In his most recent role, Dr Byon was the Vice President of Clinical Development at Fate Therapeutics, where he oversaw the Hematology portfolio, including five assets in B-cell

malignancies, AML, and Multiple Myeloma. He was crucial in restructuring the Clinical Development team and directed all Hematology trials.

Before joining Fate, he served as Senior Medical Director at Lyell Immunopharma, leading clinical strategy development, establishing the internal clinical science function, and representing clinical development in joint collaborations. At Juno Therapeutics, as Senior Medical Director, he played a significant role in the clinical development of orvacabtagene autoleucel for multiple myeloma and other novel CAR T-cell targets.

**Roadshow investor webinar with Professor Yuman Fong**

Managing Director and CEO Leslie Chong and CF33 co-inventor Professor Yuman Fong hosted an investor webinar in July as part of Professor Fong's roadshow and visit to Australia after being invited to be the keynote speaker at the 2023 Bioshares Biotech Summit. A replay of the webinar can be accessed at the provided link: https://us02web.zoom.us/webinar/register/WN_n78krTj0REuFQvpiguvsuQ

**$35m Placement and $18.2m SPP**

In conjunction with the azer-cel acquisition, Imugene secured firm commitments for a $35 million placement with the issue of approximately 416.7m new shares at $0.084 per share. This Placement gained robust support from company directors and management, who committed ~$840,000. The Company also completed a Share Purchase Plan (SPP), raising an additional $18.2 million. Funds raised are going towards payments associated with the azer-cel license agreement with Precision Biosciences Inc., including advancing the Phase 1b clinical trial for the Azer-cel Allogeneic CD19 Car-T technology.

**Financials**

At the end of the September quarter Imugene has **$163.3 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 **$22 million**, with direct research and

development and staff costs accounting for 64% 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.

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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*

# 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 2023 |

| **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 | (14,655) | (14,655) |
| | (b) product manufacturing and operating costs | | |
| | (c) advertising and marketing | | |
| | (d) leased assets | | |
| | (e) staff costs | (5,872) | (5,872) |
| | (f) administration and corporate costs | (2,527) | (2,527) |
| 1.3 | Dividends received (see note 3) | | |
| 1.4 | Interest received | 1,085 | 1,085 |
| 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** | **(21,969)** | **(21,969)** |

| **2.** | **Cash flows from investing activities** | | |
|---|---|---|---|
| 2.1 | Payments to acquire or for: | | |
| | (a) entities | | |
| | (b) businesses | (18,142) | (18,142) |
| | (c) property, plant and equipment | (4) | (4) |
| | (d) investments | | |
| | (e) intellectual property | | |
| | (f) other non-current assets | | |

| 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** | **(18,146)** | **(18,146)** |

| | | | |
|---|---|---|---|
| **3.** | **Cash flows from financing activities** | | |
| 3.1 | Proceeds from issues of equity securities (excluding convertible debt securities) | 50,618 | 50,618 |
| 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 | (49) | (49) |
| 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** | **50,569** | **50,569** |

| | | | |
|---|---|---|---|
| **4.** | **Net increase / (decrease) in cash and cash equivalents for the period** | | |
| 4.1 | Cash and cash equivalents at beginning of period | 153,151 | 153,151 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (21,969) | (21,969) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above) | (18,146) | (18,146) |

| 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) | 50,569 | 50,569 |
| 4.5 | Effect of movement in exchange rates on cash held | (215) | (215) |
| **4.6** | **Cash and cash equivalents at end of period** | **163,390** | **163,390** |

| 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 | 114,185 | 103,980 |
| 5.2 | Call deposits | 49,205 | 49,170 |
| 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)** | **163,390** | **153,151** |

| 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 | 506 |
| 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**<br>*Note: the term "facility' includes all forms of financing arrangements available to the entity.*<br>*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) | (21,969) |
| 8.2 | Cash and cash equivalents at quarter end (item 4.6) | 163,390 |
| 8.3 | Unused finance facilities available at quarter end (item 7.5) | |
| 8.4 | Total available funding (item 8.2 + item 8.3) | 163,390 |
| 8.5 | **Estimated quarters of funding available (item 8.4 divided by item 8.1)** | 7 |

*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 2023

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.