

IMUGENE LIMITED

APPENDIX 4D

Half-year ended 31 December 2022



IMUGENE
Developing Cancer
Immunotherapies

Name of entity: Imugene Limited
ABN: 99 009 179 551
Half-year ended: 31 December 2022
Previous period: 31 December 2021

Results for announcement to the market

		–%	To	–
Revenue from ordinary activities	–	–%	To	–
Loss from ordinary activities after tax attributable to members	Up	17.26%	To	(17,392,700)
Net loss for the period attributable to members	Up	17.26%	To	(17,392,700)

Distributions

No dividends have been paid or declared by the company for the current financial period. No dividends were paid for the previous financial period.

Explanation of results

Please refer to the review of operations and activities on pages 3 to 7 for explanation of the results.

This information should be read in conjunction with the 2022 annual report. Additional information supporting the Appendix 4D disclosure requirements can be found in the review of operations and activities, directors' report and the financial statements for the half-year ended 31 December 2022.

	31 December 2022 Cents	31 December 2021 Cents
Net tangible assets per security		
Net tangible asset backing (per security)	2.74	2.04

The calculation of net tangible assets excludes right-of-use assets arising from AASB 16 Leases.

Controlled entities

There have been no changes in controlled entities during the half-year ended 31 December 2022.

Other information required by Listing Rule 4.2A

- | | |
|--|-----|
| a. Details of individual and total dividends or distributions and dividend or distribution payments: | N/A |
| b. Details of any dividend or distribution reinvestment plans: | N/A |
| c. Details of associates and joint venture entities: | N/A |
| d. Other information | N/A |

Interim review

The financial statements have been reviewed by the group's independent auditor without any modified opinion, disclaimer or emphasis of matter.

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Immunotherapies

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HALF YEAR REPORT 2022

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REVIEW OF OPERATIONS & ACTIVITIES

Imugene Limited is pleased to announce its financial results for the half year ended 31 December 2022.

FINANCIAL REVIEW

The group reported a loss for the period ended 31 December 2022 of \$17,392,700 (31 December 2021: \$14,832,367). This increased loss compared to the comparative period is largely driven by the increase in clinical trial and research activities undertaken by the group.

On the back of a successful placement, institutional placement and exercise of options, the group's net assets increased to \$207,402,433 (30 June 2022: \$138,704,744). As at 31 December 2022, the group had cash reserves of \$161,908,008 (30 June 2022: \$99,887,725).

OPERATING REVIEW

Key highlights

- VAXINIA:
 - First patient dosed in VAXINIA intravenous cohort 2
 - Imugene partners with Advanced BioScience Laboratories Inc (ABL) for manufacturing of VAXINIA
 - Licence granted allowing VAXINIA Phase 1 trial expansion in Australia
- First Patient Dosed in nextHERIZON Phase 2 clinical trial
- First Patient Dosed in cohort 3 of Oncolytic Virotherapy CHECKvacc Phase I Clinical Trial
- Preclinical trial announced with Arovella's iNKT cell therapy and Imugene's onCARlytics (CF33-CD19) platform
- onCARlytics (CF33-CD19) oncolytic virus combinations presented at Society for Immunotherapy of Cancer 2022 Annual General Meeting
- Imugene selected for presentation at J.P. Morgan Healthcare Conference
- New and first CHECKvacc data presented at the 2022 San Antonio Breast Cancer Symposium
- New PD1-Vaxx data presented at the 2022 World Conference on Lung Cancer
- Imugene's HER-Vaxx & CF33 platforms featured at ASCO Gastrointestinal Cancers Symposium
- HERIZON data presented at ESMO Asia
- \$80 million raised in institution Placement to provide runway for pipeline of clinical programmes and corporate growth opportunities
- New key management appointments announced

VAXINIA

First patients dosed in VAXINIA intratumoral cohort 2 and intravenous cohort 2

In December 2022, the Phase 1 MAST (metastatic advanced solid tumours) study evaluating the safety of novel cancer-killing virus CF33-hNIS (VAXINIA) saw the first patient dosed as part of intravenous (IV) cohort 2 of the trial. This follows the clearance of IV cohort 1 in November, paving the way for the commencement of cohort 2. Subsequent to the end of the reporting period, the study cleared cohort 2 for both the IT and IV arms of the trial, allowing the opening of cohort 1 of the combination study and cohort 3 for both arms of the monotherapy dose escalation.

The multicentre 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.

Once patients in the monotherapy group have been treated with the lowest doses of VAXINIA and acceptable safety has been demonstrated, new study participants will receive combination treatment, CF33-hNIS with the immune checkpoint inhibitor pembrolizumab. This began following cohort 2 being cleared per route of administration. Overall, the study aims to recruit up to 100 patients across approximately 10 trial sites in the United States and Australia.

Licence granted allowing VAXINIA Phase 1 trial expansion in Australia

During September 2022, the Australian Government Office of the Gene Technology Regulator (OGTR) granted Imugene the DIR licence required to expand the trial within Australia. The licence, numbered DIR 192 and titled 'Clinical trial of a genetically modified (GM) chimeric Orthopoxvirus (CF33-hNIS) as a cancer treatment', is required as part of the Australian regulatory framework for dealings involving the intentional release of genetically modified organisms into the environment.

ABL and Imugene partnership to advance VAXINIA

During October 2022, Imugene announced it has partnered with Contract Development and Manufacturing Organization (CDMO) ABL, who will manufacture Imugene's VAXINIA oncolytic virus for its MAST clinical studies.

ABL has a strong background in handling a broad range of viruses, such as vaccinia, which require work under Biosafety Level 2 (BSL-2) environments and aseptic conditions. Through this collaboration, Imugene will gain access to ABL's top-of-the-line CDMO services, providing a true end-to-end solution with comprehensive analytical support, GMP manufacturing of vaccinia viruses and fill-finish of the drug product, with customizable and flexible development and manufacturing solutions.

First patient dosed in nextHERIZON Phase 2 clinical trial

During September 2022, Imugene announced that the first patient was dosed in the nextHERIZON Phase 2 clinical trial investigating Imugene's immunotherapy candidate HER-Vaxx in combination with chemotherapy or pembrolizumab in patients with HER-2+ gastric cancer. The patient was dosed at the Queen Elizabeth Hospital in Adelaide, with additional study sites to be opened.

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

First patient dosed in COHORT 3 in Phase I clinical trial of Oncolytic Virotherapy CHECKvacc

In August 2022, Imugene announced that City of Hope® had dosed the first patient in cohort 3 in the Phase I clinical trial of oncolytic virotherapy candidate CHECKvacc (CF33-hNIS-antiPDL1). The first-in-human, Phase 1, single-centre, dose-escalation study of CHECKvacc is recruiting patients with triple negative breast cancer (TNBC) and seeks to evaluate the safety and initial evidence of the efficacy of intra-tumoral administration of CF33-hNIS-antiPDL1 against metastatic TNBC.

The trial design involves a dose escalation, followed by an expansion to 12 patients at the final dose, which will be the recommended phase 2 dose (RP2D).

Preclinical Trial of Arovella's iNKT Cell Therapy and Imugene's Oncarlytics (CF33-CD19) Platform to explore potential in solid tumours

In September 2022, Imugene jointly announced with Arovella Therapeutics Ltd (ASX: ALA) that Arovella's CAR19-iNKT cell therapy platform would be tested with Imugene's onCARlytics platform to seek and destroy solid tumours. The readout from the preclinical studies performed through the collaboration is expected in H1 2023.

Imugene is evaluating a range of CD19 targeting therapies in combination with onCARlytics of which Arovella's ALA-101 will be included, allowing Arovella to benchmark its iNKT therapy for solid tumour treatment.

Arovella's lead iNKT product, ALA-101, contains a Chimeric Antigen Receptor (CAR) that targets tumour cells producing CD19 on their surface. Typically, CD19 expression is on the cell surface of blood cancers. Imugene's onCARlytics platform enables solid tumour cancers to express CD19 on their surface, which creates the opportunity to use ALA-101 to seek and destroy the solid tumour cells. Currently, ALA-101 is being developed for CD19-producing blood cancers.

Imugene Presents at Society for Immunotherapy of Cancer 2022 Annual General Meeting

The Annual Meeting of the Society for Immunotherapy of Cancer (SITC) was held in Boston, USA on 8-12 November 2022, with Imugene featured in three abstracts at the prestigious immunotherapy event.

Data from preclinical studies of Imugene's onCARlytics (CF33-CD19) oncolytic virus in combination with Celularity's placental-derived off-the-shelf allogeneic CYCART-19 T cells was presented at SITC. Dr Anthony Park from Dr Saul Priceman's lab at City of Hope presented the poster, "CF33-CD19t oncolytic virus (onCARlytics) in combination with off the-shelf allogeneic CYCART-19 T- cells targeting de novo CD19t expressing tumours".

In addition, onCARlytics in combination with Estrella's CD19-Redirected ARTEMIS® T cells was also presented at SITC. Dr Anthony Park again presented the poster, titled "CF33- CD19t oncolytic virus (onCARlytics) targets hepatocellular carcinoma (HCC) and in combination with CD19-Redirected ARTEMIS® T cells results in significant tumour killing".

onCARlytics was featured for a third time at SITC, in combination with CD19 bispecific antibody blinatumomab to target solid tumours. Dr Anthony Park presented "Combination immunotherapy using a novel chimeric oncolytic virus to redirect CD19 bispecific T cell engagers to target solid tumours".

The key findings of each presentation, as well as the posters shown at SITC, can be found on the Imugene website at: <https://www.imugene.com/conference-presentations>.

Imugene presents new and first CHECKvacc data at the 2022 San Antonio Breast Cancer Symposium

The 2022 San Antonio Breast Cancer Symposium (SABC 2022) was held on 9 December 2022 in San Antonio, Texas. Imugene presented new and first data from TNBC patients in the Phase I CHECKvacc trial.

The presentation, titled "Phase I study of intratumoral administration of CF33-hNISantiPD-L1 (CHECKvacc) in patients with metastatic triple negative breast cancer", was presented by Dr Yuan Yuan M.D., PhD, Cedars Sinai Medicine, Los Angeles and Dr Jamie Rand M.D., City of Hope, Los Angeles.

The poster presented at the event can again be viewed at:
<https://www.imugene.com/conference-presentations>

PD1-Vaxx Data Presented at 2022 World Conference on lung cancer

Imugene announced in August 2022 that data from non-small cell lung cancer patients in the Phase 1 IMPRINTER trial was presented as a poster presented at the IASLC World Conference on Lung Cancer. Professor Michael Boyer M.D., MBBS, FRACP, PhD, Chris O'Brien Lifehouse Hospital presented the poster, titled "Phase 1: IMU- 201 (PD1-Vaxx), a B-Cell Immunotherapy as Monotherapy or in Combination with Atezolizumab, in Adults with Non-Small Cell Lung Cancer".

HER-Vaxx Herizon data presented at ESMO Asia Congress 2022

Positive new data regarding overall survival results in the HER-Vaxx HERIZON study was provided in an oral presentation at the ESMO Asia Congress in Singapore during December 2022.

Principal investigator of the study, Dr Marina Maglakelidze, outlined the study design, information regarding demographics and characteristics of the 36 patients in the trial, and data covering safety and adverse events.

Key conclusions of the overall survival benefit of HER-Vaxx included:

- HER-Vaxx + chemotherapy showed a statistically significant 42% overall survival benefit compared to chemotherapy alone (13.9 vs 8.3 months)
- Duration of response is longer in the HER-Vaxx + chemotherapy arm over chemotherapy alone (30 vs 19 weeks)
- Vaccination with HER-Vaxx induced persistent HER-2 specific antibodies which correlated with clinical response as proof of concept for a first-in-class B-cell immunotherapy based on HER-2 peptides
- No significant additive toxicity was seen when HER-Vaxx was administered in combination with chemotherapy. The full presentation provided at ESMO can be viewed at: <https://www.imugene.com/conference-presentations>

OTHER EVENTS

\$80 million institutional Placement

In September 2022, the Company announced that it had received firm commitments for an \$80 million Placement at \$0.20 per share led by two leading institutional investors with significant healthcare and biotechnology expertise. The funds raised have provided an extended runway for Imugene's deep pipeline of clinical programmes and corporate growth opportunities.

BOARD AND MANAGEMENT APPOINTMENTS

Dr Jakob Dupont, Non-Executive Director

In September 2022, Imugene announced the appointment of Dr Jakob Dupont as a Non-Executive Director. Dr Dupont is an industry and drug development expert with more than 20 years of experience specialising in oncology and other therapeutic areas. Dr Dupont's experience includes NASDAQ-listed Atara Biotherapeutics (NASDAQ: ATRA), where he oversaw all research and development, including three clinical stage programs spanning Phase 1 through to Phase 3, and numerous preclinical programs.

Dr Sharon Yavrom, Executive Director, Clinical Scientist

The accomplished Dr Sharon Yavrom joined the Company as Executive Director, Clinical Scientist in July 2022. Dr Yavrom is a clinical scientist with nearly 20 years of industry experience, holding positions at industry leading companies such as TAP Pharmaceuticals, Amgen and BMS.

Mike Tonroe, Chief Financial Officer

Imugene appointed Mike Tonroe as Chief Financial Officer in September 2022. Mr Tonroe has extensive experience as a CFO and Company Secretary within the biopharmaceutical industry. He brings international finance leadership experience, having worked in the US, Canada, UK and Hong Kong, and Australia. Most recently, Mr Tonroe was CFO and Company Secretary at ASX-listed Opthea Limited and Genetic Technologies Limited, and before that was in the same role for private business Australian Synchrotron Company Ltd. These tenures included management of the US IPO and NASDAQ listing of Opthea along with M&A, restructuring, capital raising and leading the finance function across these businesses.

Adding to the depth of Mr Tonroe's experience, he has exposure to the technology, energy and travel sectors from earlier roles, including time with major accounting firms KPMG and Deloitte.

Dr Giovanni Selvaggi, Chief Medical Officer

In October, Dr Giovanni Selvaggi joined Imugene as Chief Medical Officer. A pulmonologist trained in thoracic malignancies with a focus on lung cancers and mesothelioma, he has over a decade of experience in the pharmaceutical industry. Dr Selvaggi held a pivotal role in Novartis' successful development and approval of ceritinib (or Zykadia, targeting nonsmall cell lung cancer/NSCLC) and was part of the immunotherapy team at Bristol Myers Squibb that led to the approval of nivolumab (Opdivo) in third line small cell lung cancer.

Paul Wright, Vice President CMC (Chemistry, Manufacturing and Controls)

Paul Wright was appointed to the role of Vice President CMC (Chemistry, Manufacturing and Controls). Mr Wright is an accomplished bioprocess development leader with over 25 years of experience in the fields of protein and virus production. He spent 21 years at Pfizer holding positions of increasing responsibility within the Global Manufacturing and Vaccine Research and Development organisations. Most recently he led a team responsible for the process, analytical, and formulation development of cancer vaccine projects from preclinical to first-in-human study stage.

EVENTS SINCE THE END OF THE HALF YEAR

Imugene presents at J.P. Morgan Healthcare Conference

Post the end of the reporting period, Imugene's CEO Leslie Chong presented at the 41st Annual J.P. Morgan Healthcare Conference in San Francisco.

The event is one of the largest and most prestigious on the healthcare and biotechnology industry calendar each year, with more than 3,000 global investors in attendance at the 2022 event.

The audio replay accompanied by slides can be viewed at:
<https://www.youtube.com/watch?v=vuneDZVb51g&t=4s>

Imugene's HER-Vaxx & CF33 platforms featured at ASCO Gastrointestinal Cancers Symposium

The ASCO Gastrointestinal Cancers Symposium, was held on 19-21 January 2023 in San Francisco, California. The 20th annual international event highlights the latest developments and breakthroughs in the field of gastrointestinal oncology, attended by more than 4,000 scientific figures, clinical researchers, academics, oncologists and medical practitioners from around the world.

Imugene presented its updated data from the HER-Vaxx HERIZON study in an oral presentation, trial in progress for NextHERIZON and 2 abstracts for CF33 technologies at this symposium across four separate sessions. The slides and posters presented are available at <https://www.imugene.com/conference-presentations>

VAXINIA trial advances to Combination Cohort 1 & Monotherapy Cohort 3

In February 2023, Imugene announced that its Phase 1 MAST (metastatic advanced solid tumours) study evaluating the safety of novel cancer-killing virus CF33-hNIS (VAXINIA) cleared cohort 2 of both the intravenous and intratumoral arms of the monotherapy trial, allowing it to open cohort 1 of the combination study (with Pembrolizumab) and cohort 3 for both arms of the monotherapy dose escalation.

For and on behalf of the company,



Leslie Chong
CEO and Managing Director

DIRECTOR'S REPORT

Directors

The following persons were directors of Imugene Limited during the half-year and up to the date of this report:

- Mr Paul Hopper, Executive Chairman
- Ms Leslie Chong, Chief Executive Officer and Managing Director
- Mr Charles Walker, Non-Executive Director
- Dr Lesley Russell, Non-Executive Director
- Dr Jens Eckstein, Non-Executive Director
- Dr Jakob Dupont, Non-Executive Director (appointed on 7 September 2022)

Review of operations and activities

Information on the financials and operations of the group and its business strategies and prospects is set out in the review of operations and activities on pages 3 to 7 of this interim financial report.

Significant changes in the state of affairs

In September 2022, Imugene Limited completed a Placement to raise \$80,000,000 by issuing 400,000,000 shares at \$0.20 per share. Additionally, 200,000,000 options were issued to partaking investors as free-attaching options exercisable at \$0.33.

In the opinion of the directors there were no other significant changes in the state of affairs of the group that occurred during the period.

Matters subsequent to the end of the period

No matter or circumstance has arisen since 31 December 2022 that has significantly affected, or may significantly affect:

- (a) the group's operations in future financial periods, or
- (b) the results of those operations in future financial periods, or
- (c) the group's state of affairs in future financial periods.

Auditor's independence declaration

A copy of the auditor's independence declaration as required under section 307C of the Corporations Act 2001 is set out on page 11.

Rounding of amounts

The company is of a kind referred to in ASIC Legislative Instrument 2016/191, relating to the 'rounding off' of amounts in the directors' report and financial report. Amounts in the directors' report and financial report have been rounded off to the nearest dollar in accordance with the instrument.

This report is made in accordance with a resolution of directors.



Mr Paul Hopper
Executive Chairman

Sydney

28 February 2023

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Auditor's Independence Declaration

To the Directors of Imugene Limited

In accordance with the requirements of section 307C of the *Corporations Act 2001*, as lead auditor for the review of Imugene Limited for the half year ended 31 December 2022, I declare that, to the best of my knowledge and belief, there have been:

- a no contraventions of the auditor independence requirements of the *Corporations Act 2001* in relation to the audit; and
- b no contraventions of any applicable code of professional conduct in relation to the review.



Grant Thornton Audit Pty Ltd
Chartered Accountants



T S Jackman
Partner – Audit & Assurance
Melbourne, 28 February 2023



IMUGENE

Developing Cancer Immunotherapies

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Half Year Report 2022

**FINANCIAL
STATEMENTS**

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the half-year ended 31 December 2022

	Notes	2022 \$	2021 \$
Other income	2(a)	4,813,301	5,345,608
Other losses		(779,249)	(31,812)
General and administrative expenses		(9,255,098)	(6,690,202)
Research and development expenses		(12,650,912)	(13,831,721)
Operating loss		(17,871,958)	(15,208,127)
Finance income - net		479,258	375,760
Loss before income tax		(17,392,700)	(14,832,367)
Income tax expense		-	-
Loss for the period		(17,392,700)	(14,832,367)
Other comprehensive income			
<i>Items that may be reclassified to profit or loss:</i>			
Exchange differences on translation of foreign operations		12,307	(314)
Total comprehensive loss for the period		(17,380,393)	(14,832,681)
		Cents	Cents
Loss per share for loss attributable to the ordinary equity holders of the company:			
Basic and diluted loss per share	10	(0.28)	(0.27)

The above consolidated statement of profit or loss and other comprehensive income should be read in conjunction with the accompanying notes.

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

As at 31 December 2022

	Notes	31 December 2022 \$	30 June 2022 \$
Assets			
<i>Current assets</i>			
Cash and cash equivalents		161,908,008	99,887,725
Trade and other receivables	3(a)	17,642,586	12,768,327
Other current assets		398,664	1,110,093
Total current assets		179,949,258	113,766,145
<i>Non-current assets</i>			
Other financial assets at amortised cost		217,363	252,364
Property, plant and equipment		777,461	862,786
Intangible assets	4	31,579,049	32,689,474
Other assets		19,309	34,902
Total non-current assets		32,593,182	33,839,526
Total assets		212,542,440	147,605,671
Liabilities			
<i>Current liabilities</i>			
Trade and other payables	3(b)	1,548,593	5,384,229
Other financial liabilities	3(c)	1,520,295	1,422,558
Employee benefit obligations		450,222	433,574
Other current liabilities		187,562	184,152
Total current liabilities		3,706,672	7,424,513
<i>Non-current liabilities</i>			
Other financial liabilities	3(c)	985,450	985,450
Employee benefit obligations		20,184	1,684
Other non-current liabilities		427,701	489,280
Total non-current liabilities		1,433,335	1,476,414
Total liabilities		5,140,007	8,900,927
Net assets		207,402,433	138,704,744
Equity			
Issued capital	5(a)	315,441,503	230,788,745
Other equity	5(c)	4,744,355	4,744,355
Other reserves	5(b)	8,130,391	6,692,760
Accumulated losses		(120,913,816)	(103,521,116)
Total equity		207,402,433	138,704,744

The above consolidated statement of financial position should be read in conjunction with the accompanying notes.

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

For the half-year ended 31 December 2022

	Notes	Share capital \$	Other equity \$	Other reserves \$	Accumulated losses \$	Total equity \$
Balance at 1 July 2021		113,106,912	12,097,336	5,465,460	(65,651,942)	65,017,766
Loss for the period		-	-	-	(14,832,367)	(14,832,367)
Other comprehensive loss		-	-	(314)	-	(314)
Total comprehensive loss for the period		113,106,912	12,097,336	5,465,146	(80,484,309)	50,185,085
Transactions with owners in their capacity as owners:						
Contributions of equity, net of transaction costs and tax		88,859,860	-	-	-	88,859,860
Options issued/expensed		-	-	1,627,659	-	1,627,659
Options exercised, net of transaction costs		9,980,224	-	(417,000)	-	9,563,224
Completion of Vaxinia milestones		13,441,484	(12,097,336)	-	-	1,344,148
Repayment of loaned shares to KMP		91,832	-	-	-	91,832
		112,373,400	(12,097,336)	1,210,659	-	101,486,723
Balance at 31 December 2021		225,480,312	-	6,675,805	(80,484,309)	151,671,808
Balance at 1 July 2022		230,788,745	4,744,355	6,692,760	(103,521,116)	138,704,744
Loss for the period		-	-	-	(17,392,700)	(17,392,700)
Other comprehensive income		-	-	12,307	-	12,307
Total comprehensive loss for the period		230,788,745	4,744,355	6,705,067	(120,913,816)	121,324,351
Transactions with owners in their capacity as owners:						
Contributions of equity, net of transaction costs and 5(a) tax		74,958,079	-	-	-	74,958,079
Forfeiture of options	5(b)	-	-	(56,203)	-	(56,203)
Equity-settled payments	5(b)	-	-	30,695	-	30,695
Repayment of loaned shares to KMP	5(a)	22,168	-	-	-	22,168
Options exercised	5(b)	9,672,511	-	(1,257,000)	-	8,415,511
Options issued/expensed	5(b)	-	-	2,707,832	-	2,707,832
		84,652,758	-	1,425,324	-	86,078,082
Balance at 31 December 2022		315,441,503	4,744,355	8,130,391	(120,913,816)	207,402,433

The above consolidated statement of changes in equity should be read in conjunction with the accompanying notes.

CONSOLIDATED STATEMENT OF CASH FLOWS

For the half-year ended 31 December 2022

	Notes	31 December 2022 \$	31 December 2021 \$
Cash flows from operating activities			
Payments to suppliers and employees (inclusive of GST)		(21,093,552)	(16,943,744)
Research and development tax incentive received		-	6,542,976
Net cash outflow from operating activities		(21,093,552)	(10,400,768)
Cash flows from investing activities			
Payments for property, plant and equipment		-	(7,227)
Payments for other non-current assets		-	(19,309)
Interest received		493,659	124,475
Net cash inflow from investing activities		493,659	97,939
Cash flows from financing activities			
Proceeds from issues of shares	5(a)	88,415,493	106,561,784
Share issue transaction costs		(5,041,921)	(6,140,139)
Proceeds from borrowings		-	42,000
Payments for financial liabilities		-	(1,360,650)
Principal elements of lease payments		(58,169)	(49,662)
Interest paid		(14,401)	(3,257)
Net cash inflow from financing activities		83,301,002	99,050,076
Net increase in cash and cash equivalents		62,701,109	88,747,247
Cash and cash equivalents at the beginning of the financial year		99,887,725	29,487,025
Effects of exchange rate changes on cash and cash equivalents		(680,826)	171,520
Cash and cash equivalents at end of period		161,908,008	118,405,792

The above consolidated statement of cash flows should be read in conjunction with the accompanying notes.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1 Segment information

Management has determined, based on the reports reviewed by the chief operating decision maker that are used to make strategic decisions, that the group has one reportable segment being the research, development and commercialisation of health technologies. The segment details are therefore fully reflected in the body of the financial report.

2 Profit and loss information

(a) Other income

Loss before income tax includes the following specific items:

	Consolidated entity	
	31 December 2022 \$	31 December 2021 \$
Other income		
Research and development tax incentive (i)	4,789,201	5,344,553
Other items	24,100	1,055
	4,813,301	5,345,608

(i) Research and development tax incentive

At 31 December 2022 the group accrued \$4,789,201 (2021: \$5,344,553) in relation to the research and development spend for the current period.

3 Financial assets and financial liabilities

(a) Trade and other receivables

	Consolidated entity					
	31 December 2022			30 June 2022		
	Current \$	Non-current \$	Total \$	Current \$	Non-current \$	Total \$
Accrued receivables (i)	17,537,584	- 17,537,584	12,615,735	- 12,615,735		
Other receivables	105,002	- 105,002	152,592	- 152,592		
	17,642,586	- 17,642,586	12,768,327	- 12,768,327		

(i) Accrued receivables

Accrued receivables comprise \$12,615,735 from the Australian Taxation Office in relation to the R&D tax incentive for the year ended 30 June 2022 and \$4,921,849 for the half year ended 31 December 2022 (2022: \$12,615,735).

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3 Financial assets and financial liabilities (continued)

(b) Trade and other payables

	Consolidated entity					
	31 December 2022			30 June 2022		
	Current \$	Non-current \$	Total \$	Current \$	Non-current \$	Total \$
Trade payables	738,496	-	738,496	4,513,427	-	4,513,427
Accrued expenses	810,097	-	810,097	743,440	-	743,440
Other payables	-	-	-	127,362	-	127,362
	1,548,593	-	1,548,593	5,384,229	-	5,384,229

(c) Other financial liabilities

	Consolidated entity					
	31 December 2022			30 June 2022		
	Current \$	Non-current \$	Total \$	Current \$	Non-current \$	Total \$
Expected future royalties payable (HER-Vaxx contingent consideration)	-	985,450	985,450	-	985,450	985,450
CD19 contingent consideration	1,520,295	-	1,520,295	1,422,558	-	1,422,558
	1,520,295	985,450	2,505,745	1,422,558	985,450	2,408,008

4 Intangible assets

	HER-Vaxx \$	PD1-Vaxx \$	Non PD1-Vaxx \$	CF33 \$	CD19 \$	Total \$
Half-year ended 31 December 2022						
Opening net book amount	5,765,487	115,090	278,922	20,670,942	5,859,033	32,689,474
Amortisation charge	(210,569)	(3,933)	(12,053)	(688,569)	(195,301)	(1,110,425)
Closing net book amount	5,554,918	111,157	266,869	19,982,373	5,663,732	31,579,049

The group's accounting policies and approach to assessing for indications of impairment are followed consistently in the interim financial statements as compared with the most recent annual financial statements.

5 Equity

	31 December 2022	31 December 2022	30 June 2022	30 June 2022
	No.	\$	No.	\$
Fully paid	6,421,715,706	315,441,503	5,865,699,945	230,788,745

(a) Share capital*(i) Movements in ordinary shares*

Details	Number of shares	Total \$
Balance at 1 July 2022	5,865,699,945	230,788,745
Placement of ordinary shares	400,000,000	80,000,000
Issue on the exercise of listed options	111,138,503	5,995,511
Issue on the exercise of ESOP unlisted options	44,877,258	3,677,000
Repayment of loaned shares to KMP	-	22,168
Less: Transaction costs arising on share issues	-	(5,041,921)
Balance at 31 December 2022	6,421,715,706	315,441,503

(ii) Rights of each type of share

Ordinary shares entitle the holder to participate in dividends and the proceeds on winding up of the group in proportion to the number of shares held. On a show of hands every holder of ordinary shares present at a meeting or by proxy, is entitled to one vote. Upon a poll every holder is entitled to one vote per share held. The ordinary shares have no par value.

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5 Equity (continued)

(b) Other reserves

The following table shows a breakdown of the balance sheet line item 'other reserves' and the movements in these reserves during the period. A description of the nature and purpose of each reserve is provided below the table.

Consolidated entity	Share-based payments \$	Equity Settled Payments \$	Foreign currency translation \$	Total other reserves \$
At 1 July 2022	6,740,664	-	(47,904)	6,692,760
Currency Translation differences	-	-	12,307	12,307
Other comprehensive income	-	-	12,307	12,307
Transactions with owners in their capacity as owners				
Issue of options	2,707,832	-	-	2,707,832
Exercise of options	(1,257,000)	-	-	(1,257,000)
Cessation of options	(56,203)	-	-	(56,203)
Provision for forfeiture payments	-	30,695	-	30,695
At 31 December 2022	8,135,293	30,695	(35,597)	8,130,391

(i) Movement in options (share-based payment reserve)

Details	Number of options
Balance at 1 July 2022	372,982,152
Exercise of listed options	(111,015,761)
Issue of unlisted options	200,000,001
Exercise of ESOP unlisted options	(45,000,000)
Issue of ESOP unlisted options	61,756,613
Cessation of ESOP unlisted options	(266,666)
Cessation of listed options	(124,408)
Balance at 31 December 2022	478,331,931

(c) Other equity

	31 December 2022 \$	30 June 2022 \$
Contingent issue of equity	4,744,355	4,744,355

Contingent issue of equity includes amounts related to the value of consideration shares to be issued to the previous Vaxinia Pty Ltd shareholders once certain milestones are met as per their agreement. For more information, please refer to note 7(b).

6 Share-based payments

(a) Employee share option plan (ESOP)

The assessed fair value of options at grant date was determined using the Black-Scholes option pricing model that takes into account the exercise price, term of the option, security price at grant date and expected price volatility of the underlying security, the expected dividend yield, the risk-free interest rate for the term of the security and certain probability assumptions.

The model inputs for options re-valued and granted under ESOP during the half-year 31 December 2022 included:

Grant date	Expiry date	Exercise price (\$)	No. of options	Share price at grant date (\$)	Expected volatility	Dividend yield	Risk-free interest rate	Fair value at grant date (\$)
2022-07-01	2026-06-30	0.400	3,000,000	0.195	88.10%	0.00%	3.01%	541,500
2022-07-01	2026-06-30	0.188	1,540,000	0.195	88.30%	0.00%	3.01%	201,587
2022-07-01	2026-06-30	0.306	39,263,618	0.195	88.50%	0.00%	3.01%	4,417,156
2022-09-19	2026-09-18	0.188	3,875,000	0.220	88.10%	0.00%	3.41%	574,275
2022-09-30	2026-09-29	0.184	1,700,000	0.180	88.50%	0.00%	3.57%	199,071
2022-10-01	2026-09-30	0.240	14,000,000	0.180	88.50%	0.00%	3.57%	1,502,200
2022-12-20	2027-01-09	0.154	604,461	0.145	88.40%	0.00%	3.30%	54,039
2022-12-22	2027-01-03	0.142	<u>773,534</u>	0.145	88.40%	0.00%	3.30%	76,888
			<u>64,756,613</u>					

7 Contingencies

(a) PD-1 and Non PD-1 intellectual property

The group signed an exclusive licence with the Ohio State University and Mayo Clinic on 6 June 2018 to 16 issued patents or pending applications comprising PD-1 and Non PD-1 intellectual property. As a result, the group has incurred liabilities contingent on future events in respect of each agreement (i.e. the separate PD-1 and Non PD-1 agreements):

- **Royalties on sales:** 3 percent of sales where annual turnover is less than US\$1 billion; 4 percent where annual turnover is greater than US\$1 billion
- **Milestone fees:** Up to US\$250,000 payable upon dosing of the first patient in each phase of a clinical trial; US\$1,000,000 payable upon first commercial sale
- **Annual licence fees:** US\$250,000 per annum payable contingent on first commercial sale
- **Sublicence fees:**
 - 25 percent of sublicensing consideration prior to first patient dosing in Phase I clinical trial
 - 15 percent of sublicensing consideration prior to first patient dosing in Phase II clinical trial
 - 10 percent of sublicensing consideration prior to first patient dosing in Phase III clinical trial
 - 8 percent of sublicensing consideration after first patient dosing in Phase III clinical trial

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7 Contingencies (continued)

(b) CF33 intellectual property

The key financial terms of the purchase include a cash payment of \$97,588 and the issue of 127,994,355 shares in Imugene Limited. There is a deferred consideration element of three earnout components should certain milestones be achieved:

Milestone	Description	Consideration shares	Value
1.	Allowance of investigational new drug by the US Food and Drug Administration in relation to CF33	119,354,838	\$6,325,806
2.	Dosing of first patient in a Phase 1 clinical trial for CF33	134,258,064	\$7,115,677
3.	Meeting Phase 1 safety endpoints excluding efficacy and dose	149,193,548	\$7,907,258

At the end of the current reporting period, milestones 1 & 2 have been met and were settled in shares. Management has determined that milestone 3 will be met with 60% certainty and have accounted for this accordingly by providing for a contingent issue of equity.

Also, the group separately signed the Exclusive License Agreement (“the Agreement”) with the City of Hope (“COH”) to acquire a worldwide exclusive license (“the License”) to the promising oncolytic virus technology, known as CF33, developed at City of Hope, a world-renowned independent research and treatment centre for cancer, diabetes and other life-threatening diseases based in Los Angeles, California. A cash payment of US\$3 million has been paid as part of the key financial terms of the purchase. The group has also incurred liabilities contingent on future events in respect of the License, which are summarised below:

Development Milestone Payments: Up to US\$1.5m payable to the COH upon meeting various milestones:

Milestone	Deadline	Requirement	Payment to COH
1.	8 July 2021	To dose the first patient in a Phase 1 clinical trial of CF33	US\$0.15m
2.	8 July 2023	To dose the first patient in a Phase 2 clinical trial of CF33	US\$0.3m
3.	8 July 2026	To dose the first patient in a Phase 3 clinical trial of CF33	US\$1m
4.	8 July 2029	Receive marketing approval in the US for CF33	US\$3m
5.	No deadline	Receive marketing approval in any jurisdiction other than the US	US\$1.5m

At the end of the current reporting period, milestone 1 has been met and has been settled with a payment of cash. Management believes it is uncertain whether other milestones will be met due to several factors which are outside the group’s control which affect this outcome. Due to the level of uncertainty, at 31 December 2022, none of these milestones have been accounted for on the Statement of Financial Position (30 June 2022: none).

7 Contingencies (continued)

(b) CF33 intellectual property (continued)

Sales Milestone Payments:

Once the following Milestones have been met, the group will have paid a total of US\$150 million.

- **Milestone 1:** Net sales first totalling US\$125 million.
- **Milestone 2:** Net sales first totalling US\$250 million.
- **Milestone 3:** Net sales first totalling US\$500 million.
- **Milestone 4:** Net sales first totalling US\$1 billion.

Due to the level of uncertainty, at 31 December 2022, none of these milestones have been accounted for on the Statement of Financial Position (30 June 2022: none)

Royalties on net sales:

The group is obliged to pay COH royalties on net sales based on industry standard single digit loyalty rates. This has no effect on the figures reported as at 31 December 2022 (30 June 2022: none).

CD19 intellectual property

The group signed the Exclusive License Agreement (“the Agreement”) with the City of Hope (“COH”) to acquire a worldwide exclusive license (“the License”) to the promising CAR-T technology, known as CD19, developed at City of Hope, a world-renowned independent research and treatment centre for cancer, diabetes and other life-threatening diseases based in Los Angeles, California. A cash payment of US\$4 million has been paid as part of the key financial terms of the purchase. The group has also incurred liabilities contingent on future events in respect of the License, which are summarised below:

Development Milestone Payments: Up to US\$6.55m payable to the COH upon meeting various milestones:

Milestone	Requirement	Payment to COH
1.	Upon the earlier of (a) initiation of cGMP manufacturing or (b) submission of a IND., in each case, for a Licensed Product expressing a target protein other than CD19, including expression of CD19 in conjunction with another target protein.	US\$1m
2.	Dosing of the first patient in the first Phase 1 Clinical Trial anywhere in the Territory.	US\$0.1m
3.	Dosing of the first patient in the first Phase 2 Clinical Trial anywhere in the Territory.	US\$0.2m
4.	Dosing of the first patient in the first Phase 3 Clinical Trial anywhere in the Territory.	US\$0.75m
5.	Upon the first Marketing Approval in the United States.	US\$3m
6.	Upon the first Marketing Approval in any jurisdiction other than the United States.	US\$1.5m

At the end of the current reporting period, management expects milestone 1 to be met with 95% certainty and milestone 2 with 80% certainty. These milestones have been accounted for by the provision of contingent consideration. Management believes it is uncertain whether other milestones will be met due to several factors which are outside the group's control which affect this outcome. Due to the level of uncertainty, at 31 December 2022, none of these milestones have been accounted for on the Statement of Financial Position (30 June 2022: none).

7 Contingencies (continued)

(c) CD19 intellectual property (continued)

Sales Milestone Payments:

Once the following Milestones have been met, the group will have paid a total of US\$115 million.

- **Milestone 1:** Net sales first totalling US\$125 million.
- **Milestone 2:** Net sales first totalling US\$250 million.
- **Milestone 3:** Net sales first totalling US\$500 million.
- **Milestone 4:** Net sales first totalling US\$1 billion.

Due to the level of uncertainty, at 31 December 2022, none of these milestones have been accounted for on the Statement of Financial Position (30 June 2022: none).

Royalties on net sales:

The group is obliged to pay COH royalties on net sales based on industry standard single digit royalty rates. This has no effect on the figures reported as at 31 December 2022 (30 June 2022: none).

(c) Share arrangement

The group agreed to granting Charles Walker \$300,000 worth of shares in the group during the 2014 AGM for his services as Chief Executive Officer. Part of the agreement included that if or when he sold the shares, he would be required to repay Imugene the \$300,000. If a portion of shares were sold, he is required to pay a portion of the outstanding sum to the company.

At 31 December 2022 the loan had been fully repaid to Imugene.

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8 Commitments

(a) Research and development commitments

The group had research and development commitments at 31 December 2022 in respect of:

(i) Arginine modulator intellectual property

On 13 December 2016, the group announced it had entered into an agreement with Baker IDI Heart and Diabetes Institute Holdings Limited where a contingent liability exists relating to the commercialisation of arginine modulator intellectual property. As at 31 December 2022, no liability was recognised on the basis that commercialised income cannot be reliably measured.

(ii) PD-1 and Non PD-1 intellectual property

The group signed an exclusive licence with the Ohio State University and Mayo Clinic on 6 June 2018 to 16 issued patents or pending applications comprising PD-1 and Non PD-1 intellectual property. As a result, the group has incurred the following commitments in respect of each agreement (i.e. the separate PD-1 and Non PD-1 agreements):

Maintenance fees: Up to US\$100,000 payable annually each anniversary of the agreement, until the date of first commercial sale.

In a third agreement, separate to the PD-1 and Non PD-1 licensing agreements, the group has a commitment to pay US\$551,250 per annum to cover ongoing research costs by the Ohio State University for the financial year ending 30 June 2023. These payments are for work yet to be performed as at 31 December 2022.

(iii) CF33 intellectual property

The group had number of commitments in relation to the Agreement signed with City of Hope per the below:

Licensee Diligence: The group is required to spend research and development commitments to develop CF33 in relation to the Agreement entered with the COH:

Milestones	Requirement
1.	To spend not less than US\$6m on the development of CF33
2.	To dose the first patient in a Phase 1 clinical trial of CF33
3.	To spend not less than US\$9m, in addition to the US\$6m spent for Milestone 1, on the development of CF33
4.	To dose the first patient in a Phase 2 clinical trial of CF33
5.	To dose the first patient in a Phase 3 clinical trial of CF33
6.	Receive marketing approval in the US for CF33

At 31 December 2022, Milestones 1,2 and 3 have been completed with the remaining still outstanding.

License maintenance fee: Non-refundable annual licence fee is payable to COH of US\$50,000. Payment is required on or before 10th business day after the beginning of each license year (excluding first license year ending 31 December 2019).

(iv) CD19 intellectual property

The group had the following commitments in relation to the Agreement signed with City of Hope:

License maintenance fee: Non-refundable annual license fee is payable to City of Hope of US\$50,000. This is payable on or before the tenth business day after the beginning of each License Year (excluding the first Licence Year ending December 31, 2021).

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9 Events occurring after the reporting period

No matter or circumstance has occurred subsequent to period end that has significantly affected, or may significantly affect, the operations of the group, the results of those operations or the state of affairs of the group or economic entity in subsequent financial periods.

10 Loss per share

(a) Reconciliation of earnings used in calculating loss per share

	Consolidated entity	
	31 December 2022 \$	31 December 2021 \$
<i>Basic and diluted loss per share</i>		
Loss attributable to the ordinary equity holders of the company used in calculating loss per share:		
From continuing operations	(18,974,151)	(14,832,367)
From discontinued operation	-	-
	<u>(18,974,151)</u>	<u>(14,832,367)</u>

(b) Weighted average number of shares used as denominator

	Consolidated entity	
	31 December 2022 Number	31 December 2021 Number
Weighted average number of ordinary shares used as the denominator in calculating basic and diluted loss per share	6,132,016,636	5,439,586,966

The outstanding options as at 31 December 2022 are considered to be anti-dilutive and therefore were excluded from the diluted weighted average number of ordinary shares calculation.

11 Basis of preparation of interim report

These condensed consolidated financial statements for the half-year reporting period ended 31 December 2022 have been prepared in accordance with accounting standard AASB 134 Interim Financial Reporting and the Corporations Act 2001. These financial statements also comply with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB).

These condensed consolidated financial statements do not include all the notes of the type normally included in an annual financial report. Accordingly, this report is to be read in conjunction with the annual report for the year ended 30 June 2022 and any public announcements made by Imugene Limited during the interim reporting period in accordance with the continuous disclosure requirements of the Corporations Act 2001 and ASX Listing Rules.

The accounting policies adopted are consistent with those of the previous financial year and corresponding interim reporting period.

Significant judgements, estimates and assumptions made by management in the preparation of the interim report, including the key sources of estimation uncertainty, are updated for the reporting date and consistent with those applied in annual report for the year ended 30 June 2022.

There have been no material changes to the critical judgements made or the basis of estimation for significant estimates between the previous annual report and this interim report. Changes in estimated amounts arise from changes in performance rather than changes in the basis of estimation, as shown in the relevant notes to this interim report.

In the directors' opinion:

- (a) the financial statements and notes set out on pages 13 to 26 are in accordance with the Corporations Act 2001, including:
 - (i) complying with AASB 134 *Interim Financial Reporting*, the Corporations Regulations 2001 and other mandatory professional reporting requirements, and
 - (ii) giving a true and fair view of the consolidated entity's financial position as at 31 December 2022 and of its performance for the half-year ended on that date, and
- (b) there are reasonable grounds to believe that the company will be able to pay its debts as and when they become due and payable.

This declaration is made in accordance with a resolution of directors.



Mr Paul Hopper
Executive Chairman

Sydney
28 February 2023

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Independent Auditor's Review Report

To the Members of Imugene Limited

Report on the half year financial report

Conclusion

We have reviewed the accompanying half year financial report of Imugene Limited (the Company) and its subsidiaries (the Group), which comprises the consolidated statement of financial position as at 31 December 2022, and the consolidated statement of profit or loss and other comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the half year ended on that date, a description of accounting policies, other selected explanatory notes, and the directors' declaration.

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the accompanying half-year financial report of Imugene Limited does not comply with the *Corporations Act 2001* including:

- a giving a true and fair view of the Imugene Limited's financial position as at 31 December 2022 and of its performance for the half year ended on that date; and
- b complying with Accounting Standard AASB 134 *Interim Financial Reporting and the Corporations Regulations 2001*.

Basis for Conclusion

We conducted our review in accordance with ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity*. Our responsibilities are further described in the Auditor's Responsibilities for the Review of the Financial Report section of our report. We are independent of the Company in accordance with the auditor independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)* (the Code) that are relevant to our audit of the annual financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

Directors' responsibility for the half-year financial report

The Directors of the Company are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the Directors determine is necessary to enable the preparation of the half-year financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

Auditor's responsibility

Our responsibility is to express a conclusion on the half-year financial report based on our review. We conducted our review in accordance with Auditing Standard on Review Engagements ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity*, in order to state whether, on the basis of the procedures described, we have become aware of any matter that makes us believe that the half year financial report is not in accordance with the *Corporations Act 2001* including giving a true and fair view of the Group's financial position as at 31 December 2022 and its performance for the half-year ended on that date, and complying with Accounting Standard AASB 134 *Interim Financial Reporting and the Corporations Regulations 2001*.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.



Grant Thornton Audit Pty Ltd
Chartered Accountants



T S Jackman
Partner – Audit & Assurance
Melbourne, 28 February 2023

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