

Imugene Limited

Appendix 4D and Interim report:

half-year ended
31 December 2019

Imugene Limited

Appendix 4D

Half-year ended 31 December 2019

Name of entity:	Imugene Limited
ABN:	99 009 179 551
Half-year ended:	31 December 2019
Previous period:	30 June 2019

Results for announcement to the market

					\$
Revenue from ordinary activities	-	-%	to	-	
Loss from ordinary activities after tax attributable to members	Up	38.9%	to	4,790,607	
Net loss for the period attributable to members	Up	38.9%	to	4,790,607	

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 1 to 8 for explanation of the results.

This information should be read in conjunction with the 2019 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 2019.

Net tangible assets per security

	31 December 2019 Cents	31 December 2018 Cents
Net tangible asset backing (per security)	0.78	0.66

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

Changes in controlled entities

On 18 November 2019, the group acquired 100% of the issued shares in Vaxinia Pty Ltd. For more information, please refer to Note 11(b).

There have been no other changes in controlled entities during the half-year ended 31 December 2019.

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

Imugene Limited
Appendix 4D
For the half-year ended 31 December 2019
(continued)

Interim review

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

Review of Operations & Activities

Half-year ended: 31 December 2019

Imugene Limited is pleased to announce its financial results for the half year ended 31 December 2019.

Financial Review

The group reported a loss for the year ended 31 December 2019 of \$4,790,607 (31 December 2018: \$3,449,097). This increased loss compared to the comparative period is largely due to the significant increase in clinical trial and research activities undertaken by the group.

On the back of a successful \$24.6 million capital raise (before costs) in December 2019 and the acquisition of Vaxinia Pty Ltd, the group's net assets increased to \$65,018,473 (30 June 2019 \$27,294,723). As at 31 December 2019, the group had cash reserves of \$36,767,003 (30 June 2019: \$19,047,914).

Operating Review

CF33

In November, 2019, the company completed the acquisition of Vaxinia Pty Ltd and a worldwide exclusive license to a promising oncolytic virus technology, known as CF33, developed at City of Hope, a world-renowned independent research and treatment centre for cancer based in Los Angeles, California.

CF33 is a chimeric vaccinia poxvirus from the lab of Professor Yuman Fong, Chair of Surgery at City of Hope, and a noted expert in the oncolytic virus field.

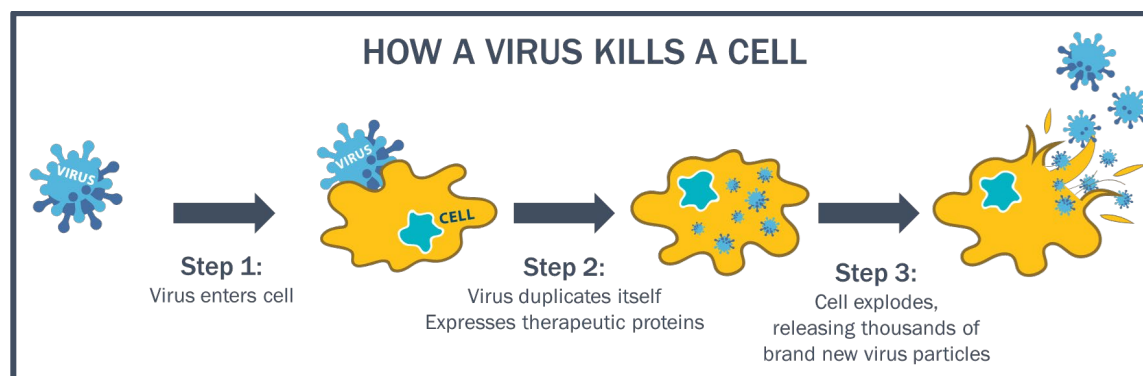
Oncolytic virotherapy (OV) utilizes naturally occurring or genetically modified viruses to infect, replicate in, and kill cancer cells, while sparing healthy cells.

C33 is a chimeric poxvirus derived through recombination among multiple strains of vaccinia virus and other species of poxvirus, thus it is better than a virus based on a single strain. One hundred chimeric orthopoxviruses and 100 chimeric parapoxviruses were generated.

Preclinical data has demonstrated that CF33 is more efficacious than all parental viruses and some viruses in clinical trials. CF33 efficiently shrank injected tumours and distant non-injected tumours in human triple negative breast cancer, colon cancer,

ovarian cancer xenograft models in mice without adverse effects at a dose that is 2-5 orders of magnitude lower than doses used for oncolytic viruses under clinical testing.

CF33 showed superior replication and cancer cell killing in NCI-60 cell lines and is more potent than all the parental and competitor viruses in most of the NCI-60 cell lines except for a few cell lines in which none of the viruses showed any effect.



CF33: Clinical Trials: CHECKVacc (CF33+hNIS+aPD-L1) and VAXINIA (CF33+hNIS)

During the half year, management have been working towards clinical development of CF33. CF33 has been developed in two different constructs: 'Vaxinia' (CF33-hNIS) and CHECKVacc (CF33-hNIS-antiPDL1). Both constructs contain a functional human iodide symporter (hNIS) gene enabling both tracking of virus and radioiodine therapy. CHECKVacc is additionally 'armed' with a checkpoint inhibitor anti-PD-L1 protein to elicit local immune changes consistent with changing tumors to a 'hot' immunological environment.

VAXINIA

The company plans to conduct a first in human Phase I/2, open-label, non-randomized, dose-escalating multi-centre study interrogating intratumoral (IT) and intravenous (IV) administration routes of 'Vaxinia' CF33-hNIS study, potential indications may include patients with metastatic lung, TNBC, melanoma, bladder, GI, colorectal tumors refractory to standard therapy or for which no standard therapy exists.

The primary objectives will be to determine safety and efficacy of CF33-NIS in multiple tumour types and evaluate safety in accordance to CTCAE 5.0 criteria, establish a maximum feasible dose for possible further combinations with immune checkpoint

inhibitors (ICI) as a run in to move into the Phase 2 clinical trials to assess the viral kinetics of CF33-hNIS in multiples tumour types and to obtain therapeutic signal.

The safety of CF33-hNIS will be assessed by the evaluation of the type, frequency, and severity of adverse events (AEs), changes in clinical laboratory tests (haematological and chemistry), immunogenicity, and physical examination etc.

The trial will involve a dose escalation to evaluate intratumoral and intravenous administration to establish a maximum feasible dose followed by a run in of combination of CF33-hNIS with ICI to establish recommended phase 2 dose. The Phase 2 study could enroll up to 100 patients to evaluate therapeutic signals.

HER-Vaxx

During the half year, management continued to monitor the enrolment and data collection for the HER-Vaxx Phase 2 clinical trial. This included adding additional countries, working with oncologists on the study to ensure that eligible patients are enrolled and guiding the contract research organisation (CRO) to attentively monitor the sites and data.

Phase 1b/2 gastric cancer study

The current HER-Vaxx trial is targeting HER-2 positive gastric cancer. HER-2 positive gastric cancer was selected for this study as this type is not nearly as well served as breast cancer. Gastric cancer has slightly lower number of patients who are HER-2 positive. However, these patients have less access to the approved therapies and the disease is more severe than breast cancer offering a significant market opportunity for HER-Vaxx. Specific regions were chosen to conduct the study due to the prevailing factors of higher rates of gastric cancer, access and reimbursement of standard of care.

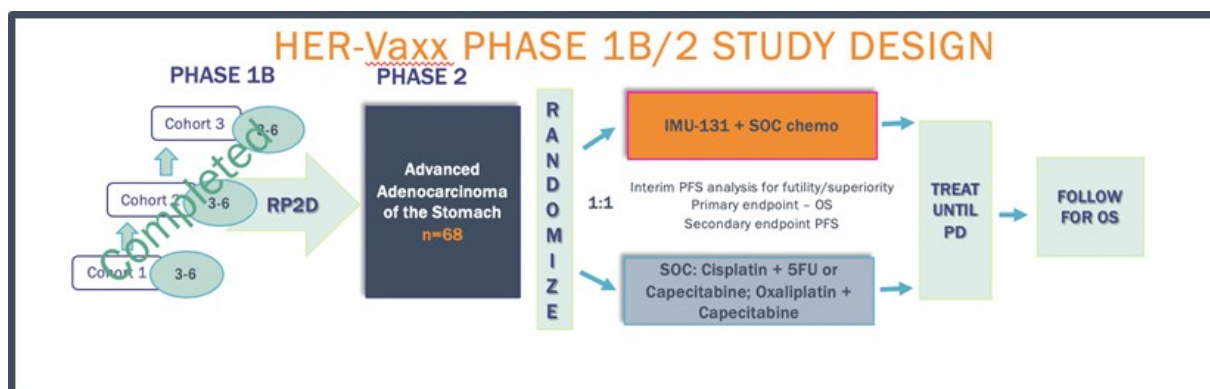
The Phase 1b stage of the study has been completed testing three different doses of the HER-Vaxx vaccine in combination with chemotherapy. Phase 1b study met all key endpoints to identify the optimal dose of HER-Vaxx for the Phase 2 study, confirmed safety and obtained additional immunological data. The company continues to monitor the patient's immune responses to the vaccine.

Additionally, Imugene presented the Phase 1b study results of its HER-Vaxx B-cell immunotherapies at the American Society of Cancer Oncology (ASCO) in Chicago, Illinois in June 2019, European Society of Medical Oncology World Congress Gastrointestinal Cancer (ESMO GI) in Barcelona, Spain in July 2019, ESMO International conference in Barcelona, Spain in November, 2019 and ESMO Asia in Singapore in December, 2019. Additional patient data from Phase 1b will be published and/or presented at international conferences in 2020.

Key results presented at the major cancer conferences included:

- 11 out of 14 evaluated patients showed clinically meaningful responses;
- Those patients that were dosed with 50 micrograms (the highest dose evaluated) showed marked increases of HER-2 specific antibody levels after vaccination;
- 2 of the 3 patients dosed with 50 micrograms demonstrated greater than 40% reduction in tumour size from baseline to day 56 (eight weeks);
- The vaccines were well tolerated and safe with antibody responses at the highest dose of 50 micrograms with no significant local or systemic reactions, and
- Trial showed clear dose-dependence of HER-2 specific antibody production.

The Phase 2 study continues to enroll patients; the objective of the Phase 2 study is to enroll ~68 patients with metastatic gastric cancer overexpressing HER-2. The patients are randomised into two arms of either HER-Vaxx plus standard-of-care chemotherapy or standard-of-care. The endpoints of this randomised trial will be overall survival, progression-free survival, immune response, and safety.



PD1-Vaxx

The company's PD1-Vaxx is a B-cell immunotherapy, peptide cancer vaccine designed to treat tumours such as lung cancer by interfering with PD-1/PD-L1 binding and interaction, and produce an anti-cancer effect similar to Keytruda, Opdivo and the other immune checkpoint inhibitor monoclonal antibodies that are transforming the treatment of a range of cancers.

The inhibitory immune pathway, consisting of the receptor programmed cell death 1 and its ligands, PD-L1 and PD-L2, plays a vital role in the maintenance of peripheral tolerance. Several tumors exploit this pathway by expressing PD-L1 and PD-L2 to escape T-cell-mediated tumor-specific and pathogen-specific immunity. Imugene is

proposing to develop an anti-PD-1 immunotherapy to treat patients with lung tumors that over-express the ligand of PD1, PD-L1/2. The hypothesis is that a polyclonal-induced B-cell antibody response will be more effective or as effective with improved safety over current monoclonal antibody therapy. Therapies with monoclonal antibodies targeting PD-1 and its ligands are associated with remarkable response rates in various cancers and have revolutionized cancer treatment.

PD1-Vaxx will be trialled in patients with non-small cell lung cancer (NSCLC), the most common type of lung cancer, accounting for around 80% of cases. The study is planned to commence in 2020 and is to be conducted at up to 6-10 sites in North America and Australia under a U.S. Food & Drug Administration (FDA) Investigational New Drug (IND) application.

PD1-Vaxx

The current PD1-Vaxx trial is targeting non small cell lung cancer (NSCLC). PD1-Vaxx will be testing three different doses to identify safety, immunological data and recommended phase 2 dose for the expansion stage of the study. The Phase 2 assumption is to expand patient enrollment to specific cancer indications.

Oncolytic Virotherapy Scientific Advisory Board

October 2019, the company appointed Professor Yuman Fong, MD, Chair of the Department of Surgery at City of Hope to head up the oncolytic virotherapy (OV) Scientific Advisory Board (SAB).



Dr. Fong is a pioneer both in the operating room and in the laboratory, Yuman Fong, M.D., The Sangiacomo Family Chair in Surgical Oncology and chair of The City of Hope Dept of Surgery is an internationally recognized expert in liver and pancreatic cancer. He has developed many new surgical techniques and instruments. He has also led research efforts to use genetically modified viruses to destroy cancer cells. Prof. Fong joined City of Hope in 2014 after more than two decades at the renowned Memorial SloanKettering Cancer Center in New York City. Prof. Fong is both an author and innovator. He has written and edited over 700 scholarly articles

as well as 14 textbooks. He is currently the Editor-in-Chief of Molecular Therapy Oncolytics (Cell Press). Prof. Fong has had leadership roles in regulatory aspects of gene therapy, including serving as Chair of the Recombinant DNA Advisory Committee of the National Institutes of Health of the United States.

November 2019, the company appointed Professor Prasad S. Adusumilli, MD FACS FCCP, Deputy Chief, Thoracic Service; Co-Director, Mesothelioma Program; Head, Solid Tumors Cell Therapy, Cellular Therapeutics Center at the Memorial Sloan Kettering Cancer Center in New York, to the newly formed OV SAB.

Dr. Adusumilli is a world-renowned thoracic surgeon with expertise in the diagnosis and treatment of cancers in the chest, lung cancer, esophageal cancer, mesothelioma, thymoma, mediastinal and chest wall tumors, and cancers metastatic to lung and pleura.



December 2019, the company appointed Dr Rebecca Auer, MD MSc FRCSC, Associate Professor, Department of Surgery and Department of Biochemistry, Microbiology and Immunology, Faculty of Medicine University of Ottawa; Surgical Oncologist, The Ottawa Hospital; Tier 2 Clinical Research Chair in Perioperative Cancer Therapeutics University of Ottawa, to its newly formed oncolytic virotherapy (OV) Scientific Advisory Board (SAB).



As a Surgeon-Scientist, Dr. Auer heads a research laboratory and is the principle investigator in related clinical trials. Her translational research program focuses on understanding the promotion of metastatic disease in the perioperative period, following surgical stress. In particular she is studying novel perioperative cancer therapies, including oncolytic viruses, cancer vaccines and targeted therapies, which inhibit the formation of metastases postoperatively.

Events since the end of the Half Year

January, 2020:

The United States Patent and Trademark Office (USPTO) granted a Notice of Grant to the Company for Patent Application 15/316868, which protects its B-Cell immunotherapy - HER-Vaxx, currently in Phase II development for HER2-positive gastric cancer.

PD1-Vaxx GMP manufacturing, including final sterile fill and finish, processes completed by FDA inspected and qualified contract manufacturing organization's (CMO) in the U.S.

The final filled and finished vials of PD1-Vaxx have completed non-human primate (NHP) safety toxicology studies at a US-based contract research organization (CRO). The NHP was chosen due to its target PD1 receptor being 100% identical to human PD1 and hence the study also provided valuable data on the antibody generating potential of PD1-Vaxx in humans.

The three doses tested not only were well tolerated with no adverse findings reported, they also generated high levels of PD1-targeting polyclonal antibodies. This is an important development as it may indicate that PD1-Vaxx will break tolerance in humans, generate antibodies, and may produce an anti-cancer effect similar to Keytruda®, Opdivo® and the other immune checkpoint inhibitor monoclonal antibodies that are transforming treatment of a range of cancers. These three doses will now be selected for the dose escalation phase of the Phase 1 trial commencing in 2020.

The study was completed under Good Laboratory Practice (GLP) conditions, a standard required for regulatory submissions to the Therapeutic Goods Administration in Australia and the US Food and Drug Administration in the US.

The company continues to gain numerous media attention. In February, 2020, Imugene was featured in Life Science Leader magazine and the Pharma Letter.



the pharma letter
* Up to date news for the Pharmaceutical and Biotechnology industries

Eligible Imugene thinking ahead to 'actively developing a BD department'

Events since the end of the Half Year

The focus of the group's operations in the short to medium term will be directed at development of CF33 and PD1-Vaxx in a first in human studies and continued enrolment of the HER-Vaxx Phase 2 study.

For and on behalf of the company



Leslie Chong
CEO and Managing Director

Imugene Limited

ABN 99 009 179 551

Interim report - 31 December 2019

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This interim financial report does not include all the notes of the type normally included in an annual financial report. Accordingly, this report should be read in conjunction with the annual report for the year ended 30 June 2019 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*.



Directors' report

Your directors present their report on the consolidated entity (referred to hereafter as the 'group') consisting of Imugene Limited and the entities it controlled at the end of, or during, the half-year ended 31 December 2019.

Directors

The following persons were directors of Imugene Limited during the whole of 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 Axel Hoos, Non-Executive Director

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 1 to 8 of this interim financial report.

Significant changes in the state of affairs

On 18 November 2019, Imugene Limited acquired 100% of the shares in Vaxinia Pty Ltd. Imugene has separately acquired worldwide exclusive licence to the promising oncolytic virus technology known as CF33 which is 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. For further detail, please refer to Note 11(b).

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 2019 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 12.

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
26 February 2020

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 2019, 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 review; 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, 26 February 2020



Financial statements

Imugene Limited
Condensed consolidated statement of profit or loss and other comprehensive income
For the half-year 31 December 2019

		Consolidated entity	
		31 December	31 December
		2019	2018
	Notes	\$	\$
Other income	2	2,374,648	1,625,316
Other gains/(losses) – net		(17,421)	91,912
General and administrative expenses		(3,021,712)	(2,064,746)
Research and development expenses		(4,233,455)	(3,290,786)
Operating loss		(4,897,940)	(3,638,304)
Finance income		110,208	192,355
Finance expenses		(2,875)	(3,148)
Finance costs - net		107,333	189,207
Loss before income tax		(4,790,607)	(3,449,097)
Income tax expense		-	-
Loss for the period		(4,790,607)	(3,449,097)
Other comprehensive income			
Other comprehensive income for the period, net of tax		-	-
Total comprehensive loss for the period		(4,790,607)	(3,449,097)
		Cents	Cents
Loss per share for loss attributable to the ordinary equity holders of the company:			
Basic/diluted loss per share	12	(0.13)	(0.10)

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

Imugene Limited
Condensed consolidated balance sheet
As at 31 December 2019

	Consolidated entity	
	31 December	30 June
	2019	2019
Notes	\$	\$
ASSETS		
Current assets		
Cash and cash equivalents	36,767,003	19,047,914
Trade and other receivables	2,548,056	4,215,170
Other current assets	606,388	160,485
Total current assets	39,921,447	23,423,569
Non-current assets		
Financial assets at amortised cost	80,000	50,000
Property, plant and equipment	192,008	233,095
Intangible assets	4(a) 30,458,449	7,057,100
Other assets	15,593	15,593
Total non-current assets	30,746,050	7,355,788
Total assets	70,667,497	30,779,357
LIABILITIES		
Current liabilities		
Trade and other payables	3(a) 2,892,190	2,233,212
Employee benefit obligations	170,316	131,804
Other current liabilities	60,212	58,590
Total current liabilities	3,122,718	2,423,606
Non-current liabilities		
Trade and other payables	3(a) 1,503,189	-
Other financial liabilities	985,450	985,450
Employee benefit obligations	756	11,272
Other non-current liabilities	36,911	64,306
Total non-current liabilities	2,526,306	1,061,028
Total liabilities	5,649,024	3,484,634
Net assets	65,018,473	27,294,723
EQUITY		
Issued capital	5(a) 92,797,564	63,122,493
Other equity	5(c) 12,097,336	-
Other reserves	5(b) 1,716,440	988,945
Accumulated losses	(41,592,867)	(36,816,715)
Total equity	65,018,473	27,294,723

The above condensed consolidated balance sheet should be read in conjunction with the accompanying notes.

Imugene Limited
Condensed consolidated statement of changes in equity
For the half-year 31 December 2019

Consolidated entity	Notes	Share capital \$	Other equity \$	Other reserves \$	Accumulated losses \$	Total equity \$
Balance at 1 July 2018		44,285,931	-	299,945	(29,110,397)	15,475,479
Loss for the period		-	-	-	(3,449,097)	(3,449,097)
Total comprehensive loss for the period		44,285,931	-	299,945	(32,559,494)	12,026,382
Transactions with owners in their capacity as owners:						
Contributions of equity, net of transaction costs and tax		18,669,982	-	-	-	18,669,982
Options exercised		166,522	-	(16,428)	-	150,094
Options forfeited/lapsed		-	-	(69,042)	69,042	-
Share-based payment expense		-	-	343,112	-	343,112
		<u>18,836,504</u>	<u>-</u>	<u>257,642</u>	<u>69,042</u>	<u>19,163,188</u>
Balance at 31 December 2018		63,122,435	-	557,587	(32,490,452)	31,189,570
Balance at 1 July 2019		63,122,493	-	988,945	(36,816,715)	27,294,723
Loss for the period		-	-	-	(4,790,607)	(4,790,607)
Total comprehensive loss for the period		63,122,493	-	988,945	(41,607,322)	22,504,116
Transactions with owners in their capacity as owners:						
Contributions of equity, net of transaction costs and tax	5(a)	22,788,650	-	-	-	22,788,650
Options issued/expensed	5(b)	-	-	644,218	-	644,218
Options exercised	5(b)	102,720	-	(25,038)	-	77,682
Options forfeited/lapsed	5(b)	-	-	(14,455)	14,455	-
Re-valuation of options awarded in prior period	5(b)	-	-	122,770	-	122,770
Acquisition of Vaxinia Pty Ltd	5	6,783,701	12,097,336	-	-	18,881,037
		<u>29,675,071</u>	<u>12,097,336</u>	<u>727,495</u>	<u>14,455</u>	<u>42,514,357</u>
Balance at 31 December 2019		92,797,564	12,097,336	1,716,440	(41,592,867)	65,018,473

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

Imugene Limited

Condensed consolidated statement of cash flows

For the half-year 31 December 2019

	Consolidated entity	
	31 December	31 December
	2019	2018
Notes	\$	\$
Cash flows from operating activities		
Payments to suppliers and employees (inclusive of GST)	(7,776,473)	(4,644,298)
Research and development tax incentive received	4,126,678	1,852,597
Net cash outflow from operating activities	(3,649,795)	(2,791,701)
Cash flows from investing activities		
Payments for financial assets at amortised cost	(30,000)	-
Payments for property, plant and equipment	(215)	(53,949)
Payments for intellectual property	4(a) (1,481,672)	-
Payments for rental deposit	-	(15,593)
Payments for term deposits	-	(29,694)
Interest received	137,498	199,303
Net cash (outflow) inflow from investing activities	(1,374,389)	100,067
Cash flows from financing activities		
Proceeds from issues of shares	5(a) 24,566,822	20,264,036
Share issue transaction costs	(1,801,077)	(1,443,960)
Principal elements of lease payments	(26,231)	(18,900)
Proceeds from other current liabilities	458	-
Interest paid	(2,875)	-
Net cash inflow from financing activities	22,737,097	18,801,176
Net increase in cash and cash equivalents	17,712,913	16,109,542
Cash and cash equivalents at the beginning of the financial year	19,047,914	7,822,057
Effects of exchange rate changes on cash and cash equivalents	6,176	121,541
Cash and cash equivalents at end of period	36,767,003	24,053,140

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

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

Loss before income tax includes the following specific items:

	Consolidated entity	
	31 December	31 December
	2019	2018
	\$	\$
Other income		
Research and development tax incentive	2,374,648	1,625,316

3 Financial assets and financial liabilities

(a) Trade and other payables

	Consolidated entity					
	31 December			30 June		
	2019			2019		
	Current	Non-current	Total	Current	Non-current	Total
	\$	\$	\$	\$	\$	\$
Trade payables	1,257,330	-	1,257,330	1,479,429	-	1,479,429
Accrued expenses	187,355	-	187,355	727,029	-	727,029
Contingent consideration	1,434,864	1,503,189	2,938,053	-	-	-
Other payables	12,641	-	12,641	26,754	-	26,754
	2,892,190	1,503,189	4,395,379	2,233,212	-	2,233,212

Contingent consideration includes amounts related to the provision of upfront license fees to City of Hope and completion of milestones. For more information, please refer to Note 8(a)(ii).

4 Non-financial assets and liabilities

(a) Intangible assets

	Consolidated entity	
	31 December	30 June
	2019	2019
	\$	\$
Patents, licences and other rights		
HER-Vaxx	6,599,755	6,599,755
PD-1	130,670	130,670
Non PD-1	326,675	326,675
CF33 (i)	23,401,349	-
	30,458,449	7,057,100

4 Non-financial assets and liabilities (continued)

(a) Intangible assets (continued)

The group's patents, licences and other rights are measured at initial cost, less any accumulated amortisation and impairment losses.

(i) CF33

The group has recognised the Intellectual Property "CF33" through the acquisition of Vaxinia Pty Ltd. For further detail, please refer to Note 11(b).

It is the board's expectation that the acquired CF33 intellectual property will generate future economic benefits for the group. The amounts recognised as intangible assets relate to the upfront licenses fee paid in respect of the licence agreement and the value of equity issued to Vaxinia Pty Ltd shareholders for the acquisition of the company, and contingent considerations. The contingent consideration arrangements require the group to pay the former owners of Vaxinia pre-determined amount upon the completion of each of 3 milestones per the license agreements. The fair value of the contingent considerations was probability-adjusted based on the directors' assumption, 90% probability of completing the milestone 1 & 2.

5 Equity

	31 December 2019 No.	31 December 2019 \$	30 June 2019 No.	30 June 2019 \$
Fully paid	4,425,970,549	92,797,564	3,609,847,749	63,122,493

(a) Share capital

(i) Movements in ordinary shares

Details	Number of shares	\$
Balance at 1 July 2019	3,609,847,749	63,122,493
Issue at \$0.0125 on exercise of ESOP unlisted options (2019-10-18)	2,500,000	31,250
Issue at \$0.0175 on exercise of ESOP unlisted options (2019-10-18)	2,500,000	43,750
Transfer from reserves on exercise of ESOP unlisted options (2019-10-18)	-	25,038
Issue at \$0.04 on exercise of IMUOB options (2019-10-18)	491	20
Shares issued at \$0.0155 for the acquisition of Vaxinia Pty Ltd (2019-11-28)	127,994,355	6,783,701
Issue at \$0.026 on exercise of IMUOA options (2019-11-28)	38,313	996
Issue at \$0.04 on exercise of IMUOB options (2019-11-28)	41,660	1,666
Issue at \$0.036 pursuant to placement (2019-12-06)	683,047,981	24,589,727
Less: Transaction costs arising on share issues	-	(1,801,077)
Balance at 31 December 2019	4,425,970,549	92,797,564

(ii) Acquisition of Vaxinia Pty Ltd

Shareholders of Vaxinia were entitled to receive 127,994,355 shares in Imugene Limited after the deal was approved. 22,039,290 shares are escrowed for a period of 6 months after issue and 105,955,065 shares are escrowed for a period of 12 months after issue. For further details, please refer to Note 11(b).

5 Equity (continued)

(a) Share capital (continued)

(iii) 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.

(b) Other reserves

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

Details	Number of options	\$
Balance at 1 July 2019	760,274,240	988,945
Forfeiture of ESOP unlisted options at \$0.025	(2,500,000)	(14,455)
Exercise of ESOP unlisted options at \$0.0125 (2019-10-18)	(2,500,000)	(12,519)
Exercise of ESOP unlisted options at \$0.0175 (2019-10-18)	(2,500,000)	(12,519)
Exercise of IMUOB listed options at \$0.04 (2019-10-18)	(491)	-
Revaluation of options awarded in prior period	-	122,770
Exercise of IMUOA listed options at \$0.026 (2019-11-28)	(38,313)	-
Exercise of IMUOB listed options at \$0.04 (2019-11-28)	(41,660)	-
Issue of IMUOC listed options at \$0.54 each (2019-12-06)	227,682,634	-
Issue of ESOP unlisted options at \$0.040 each (2019-12-06)	30,000,000	104,408
Amortised share-based payments for options issued in prior periods	-	539,810
Balance at 31 December 2019	1,010,376,410	1,716,440

(ii) Revaluation of options awarded in prior period

Options awarded to the non-executive directors on 23 April 2019 and 20 May 2019 were valued at \$757,000 with \$209,116 expensed in the 30 June 2019 financial statements. At shareholder approval (grant date) on 8 November 2019, the options were revalued in accordance with AASB2 Share Based Payments for a value of \$1,200,000 and an adjustment of 122,770 has been recorded to reflect the revaluation.

(c) Other equity

	31 December 2019 \$	30 June 2019 \$
Contingent issue of equity	12,097,336	-

Contingent issue of equity includes amounts related to the value of consideration shares to be issued to the previous Vaxinia shareholders once certain milestones are met as per their agreement. For more information, please refer to note 11(b).

6 Share-based payments

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 2019 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 per option (\$)
2019-11-08 (IMUOP20)	2022-11-08	0.04	20,000,000	0.026	90.50%	0.00%	0.88%	248,000
2019-11-08 (IMUOP21)	2022-11-08	0.042	40,000,000	0.026	90.50%	0.00%	0.88%	484,000
2019-11-08 (IMUOP22)	2022-11-08	0.045	40,000,000	0.026	90.50%	0.00%	0.88%	468,000
2019-11-18 (IMUOP23)	2022-11-18	0.04	30,000,000	0.053	93.30%	0.00%	0.75%	330,000
			130,000,000					

7 Critical estimates, judgements and errors

The preparation of financial statements requires the use of accounting estimates which, by definition, will seldom equal the actual results. Management also needs to exercise judgement in applying the group's accounting policies.

The group makes estimates and assumptions concerning the future. The resulting accounting estimates will, by definition, seldom equal the related actual results. The estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial period are discussed below.

(i) R&D tax incentive

The group's research and development activities are eligible under an Australian government tax incentive for eligible expenditure from 1 July 2011. Management has assessed these activities and expenditure to determine which are likely to be eligible under the incentive scheme. For the half-year ended 31 December 2019, the group has included an item in other income of \$2,374,648 (2018: \$1,625,316) to recognise this amount which relates to this period.

(ii) Share-based payments

The value attributed to share options issued is an estimate calculated using an appropriate mathematical formula based on an option pricing model. The choice of models and the resultant share option value require assumptions to be made in relation to the likelihood and timing of meeting the conditions of the shares and the value and volatility of the price of the shares.

8 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:**

8 Contingencies (continued)

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

- 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

(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. For further details, please refer to Note 11(b). 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

Management expects the milestone 1 and 2 to be met with certainty, however it is uncertain whether to meet milestone 3 due to number of factors which are outside the group's control affect this outcome. Hence, management has accounted for those payments in relation to the milestone 1 and 2 for this current reporting period and the group has incurred liability contingent on future event as follows:

- **Milestone fees:** \$2,312,500 payable upon meeting Phase 1 safety endpoints excluding efficacy and dose.

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. The key financial terms of the purchase include a cash payment of US\$3 million. 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

8 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.

- **Royalties on net sales:**

The group is obliged to pay COH royalties on net sales based on industry standard single digit royalty rates.

9 Commitments

(a) Research and development commitments

The group had research and development commitments at 31 December 2019 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 2019, 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\$546,000 per annum to cover ongoing research costs by the Ohio State University for the financial years ending 30 June 2020 and 2021. These payments are for work yet to be performed as at 31 December 2019.

9 Commitments (continued)

(a) Research and development commitments (continued)

(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	Deadline	Requirement
1.	8 July 2021	To spend not less than US\$6m on the development of CF33
2.	8 July 2021	To dose the first patient in a Phase 1 clinical trial of CF33
3.	8 July 2023	To spend not less than US\$9m, in addition to the US\$6m spent for Milestone A, on the development of CF33
4.	8 July 2023	To dose the first patient in a Phase 2 clinical trial of CF33
5.	8 July 2026	To dose the first patient in a Phase 3 clinical trial of CF33
6.	8 July 2029	Receive marketing approval in the US for CF33

- **Licence 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).

10 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.

11 Interests in other entities

(a) Material subsidiaries

Name of entity	Notes	Place of business/ country of incorporation	Ownership interest held by the group		Ownership interest held by non-controlling interests	
			31 December 2019	30 June 2019	31 December 2019	30 June 2019
			%	%	%	%
Biolife Science Qld Pty Ltd		Australia	100	100	-	-
Lingual Consegna Pty Ltd		Australia	100	100	-	-
Vaxinia Pty Ltd		Australia	100	-	-	-

On 18 November 2019, Imugene Limited acquired 100% of the shares in Vaxinia Pty Ltd. Vaxinia has separately acquired a worldwide exclusive licence to the promising oncolytic virus technology known as CF33 which is 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.

11 Interests in other entities (continued)

(b) Asset acquisition

The group signed the Share Sale Deed ("Deed") with Vaxinia Pty Ltd on 15 July 2019 to acquire the 100% of the shares in Vaxinia. Vaxinia is proprietary company that was only incorporated in December 2018 for the purpose of securing the right to develop and commercialise CF33.

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.

The completion of the purchase of Vaxinia and the Licence becoming effective, although each are governed by separate agreement, are contingent on each other, therefore in order for Imugene to gain the benefit of the licence and it must complete the purchase of Vaxinia.

For the purpose of the ASX reporting purposes, directors of the group evaluated the acquisition to determine whether the group of assets acquired represent a business for Australian GAAP accounting purpose and concluded that the acquired assets does not meet the definition of a business under AASB 3. On this basis, the acquired assets are initially recognised at costs.

Detail of the purchase consideration, the assets acquired are as follows:

Purchase consideration:	\$
Cash paid	1,582,260
Payable to COH	2,938,053
Issued shares (note: 5(a))	6,783,701
Contingent consideration (note: 8(b))	12,097,335
Total purchase consideration	23,401,349

Total assets and liabilities recognised as a result of the acquisition are as follows:

CF 33 Intellectual property (note: 4(a))	23,401,349
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As part of the acquisition, Imugene also acquired Vaxinia's trade payables which amounted to \$64,902. The amount has been paid in its entirety at 31 December 2019.

12 Loss per share

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

Consolidated entity	
31 December	31 December
2019	2018
\$	\$

Basic and diluted loss per share

Loss attributable to the ordinary equity holders of the company used in calculating loss per share:

From continuing operations	(4,790,607)	(3,449,097)
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12 Loss per share (continued)

(b) Weighted average number of shares used as denominator

Consolidated entity	
31 December	30 June
2019	2018
Number	Number

Weighted average number of ordinary shares used as the denominator in calculating basic and diluted loss per share	<u>3,727,634,101</u>	<u>3,337,433,821</u>
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The outstanding options as at 31 December 2019 are considered to be anti-dilutive and therefore were excluded from the diluted weighted average number of ordinary shares calculation.

13 Basis of preparation of interim report

These condensed consolidated financial statements for the half-year reporting period ended 31 December 2019 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 2019 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.

(a) New and amended standards adopted by the group

There are no new accounting standards or interpretations that affect the financial position of the company to be adopted in this reporting period.

Interpretation 23 requires the assessment of whether the effect of uncertainty over income tax treatments should be included in the determination of taxable profit (tax loss), tax bases, unused tax losses, unused tax credits and tax rates. The Interpretation outlines the requirements to determine whether an entity considers uncertain tax treatments separately, the assumptions an entity makes about the examination of tax treatments by taxation authorities, how an entity determines taxable profit (tax loss), tax bases, unused tax losses, unused tax credits and tax rates and how an entity considers changes in facts and circumstances.

The group has adopted Interpretation 23 from 1 July 2019, based on an assessment of whether it is 'probable' that a taxation authority will accept an uncertain tax treatment. This assessment takes into account that for certain jurisdictions in which the group operates, a local tax authority may seek to open a group's books as far back as inception of the group. Where it is probable, the group has determined tax balances consistently with the tax treatment used or planned to be used in its income tax filings. Where the group has determined that it is not probable that the taxation authority will accept an uncertain tax treatment, the most likely amount or the expected value has been used in determining taxable balances (depending on which method is expected to better predict the resolution of the uncertainty). There has been no impact from the adoption of Interpretation 23 in this reporting period. Other accounting pronouncements which have become effect from 1 July 2019 and have therefore been adopted do not have a significant impact on the group's financial results or position.

In the directors' opinion:

- (a) the financial statements and notes set out on pages 9 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 2019 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
26 February 2020



Independent auditor's review report to the members

Independent Auditor's Report

To the Members of Imugene Limited

Report on the audit of the 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 condensed statement of financial position as at 31 December 2019, and the consolidated condensed statement of profit or loss and other comprehensive income, consolidated condensed statement of changes in equity and consolidated condensed 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, nothing has come to our attention that causes us to believe that the half-year financial report of Imugene Limited does not give a true and fair view of the financial position of the Group as at 31 December 2019, and of its financial performance and its cash flows for the half-year ended on that date, in accordance with the *Corporations Act 2001*, including complying with Accounting Standard AASB 134 *Interim Financial Reporting*.

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 2019 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*. As the auditor of Imugene Limited, ASRE 2410 requires that we comply with the ethical requirements relevant to the audit of the annual financial report.

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.

Independence

In conducting our review, we have complied with the independence requirements of the *Corporations Act 2001*.

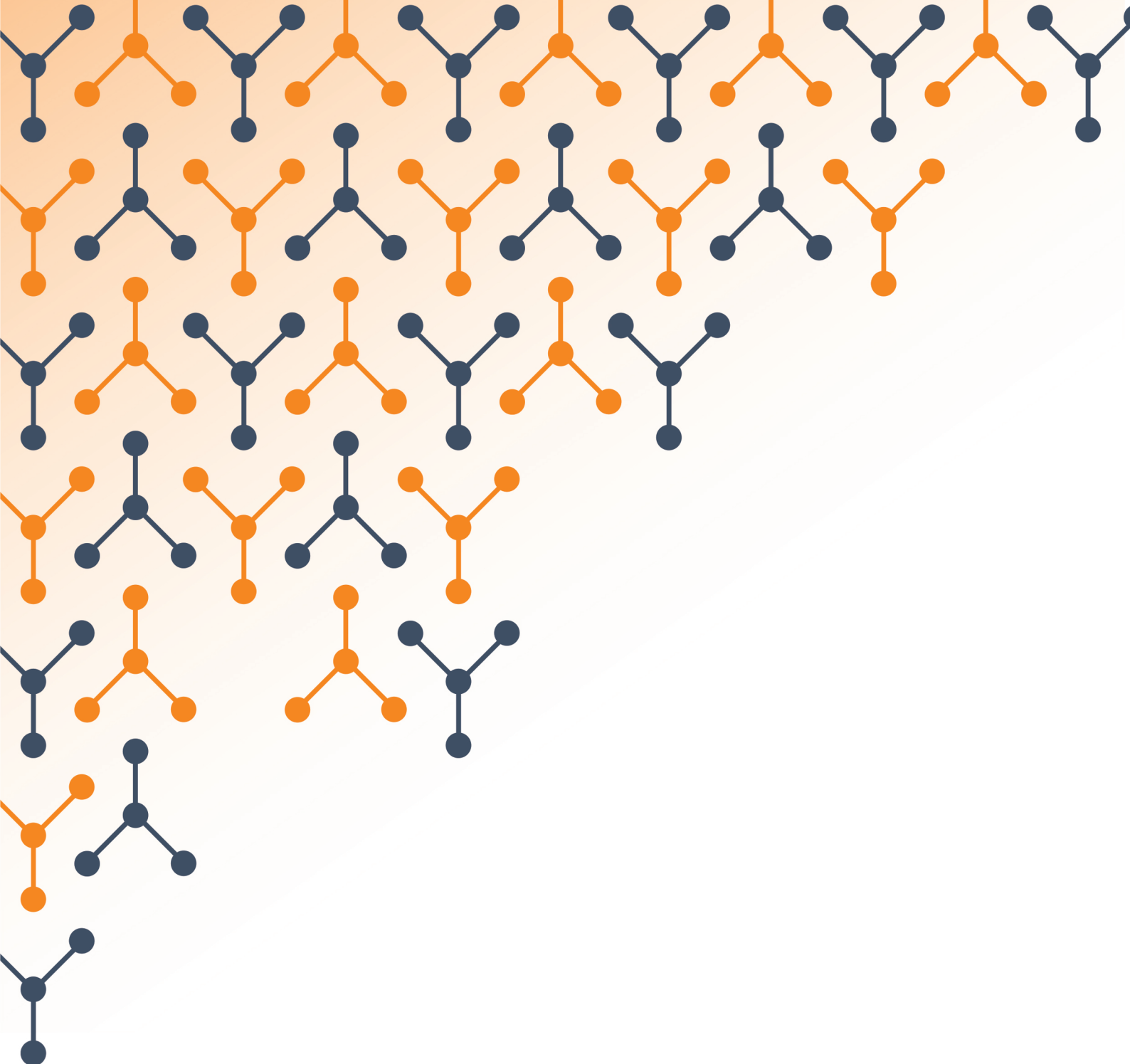


Grant Thornton Audit Pty Ltd
Chartered Accountants



T S Jackman
Partner – Audit & Assurance

Melbourne, 26 February 2020



Imugene Limited
Interim report
half-year ended
31 December 2019

IMUGENE