

half-year ended 31 December 2018



Imugene Limited Appendix 4D For the half-year ended 31 December 2018

## Imugene Limited Appendix 4D Half-year ended 31 December 2018

Name of entity:Imugene LimitedABN:99 009 179 551Half-year ended:31 December 2018Previous period:31 December 2017

#### Results for announcement to the market

\$

Revenue for ordinary activities	-	-%	to	-
Loss from ordinary activities after tax attributable to members	Up	111.2%	to	3,449,097
Net loss for the period attributable to members	Up	111.2%	to	3,449,097

#### **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 7 for explanation of the results.

This information should be read in conjunction with the 2018 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 2018.

#### Net tangible assets per security

	31 December 2018 Cents	31 December 2017 Cents
Net tangible asset backing (per security)	0.67	0.39

#### Changes in controlled entities

There have been no changes in controlled entities during the half-year ended 31 December 2018.

#### 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 2018 (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 and activities

Half-year ended: 31 December 2018

Imugene Limited is pleased to announce its financial results for the half-year ended 31 December 2018.

#### Financial review

The group reported a loss for the half-year ended 31 December 2018 of \$3,449,097 (2017: \$1,632,852). 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 \$20.1 million capital raise (before costs) in July 2018, the group's net assets increased to \$31,189,570 compared with \$15,475,479 at 30 June 2018. As at 31 December 2018, the group had cash reserves of \$24,053,140 (30 June 2018: \$7,822,057).

## **Operating review**

#### **HER-Vaxx**

Imugene's Phase 1b/2 clinical trial is targeting patients with HER-2 positive gastric cancer. The group selected HER-2 positive gastric cancer as this type is not nearly as well served as breast cancer, yet still has approximately the same number of patients being HER-2 positive and is more severe than breast cancer, offering a significant market opportunity for HER-Vaxx. Asia and Eastern Europe were the regions of choice due to the prevailing factors such as higher rates of HER-2 positive gastric cancer.

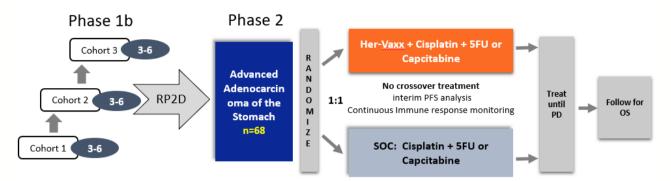
#### Phase 1b/2 gastric cancer study

The Phase 1b/2 gastric cancer study design is as follows:

- The Phase 1b lead-in trial tested three different doses of the HER-Vaxx vaccine with up to 18 patients (classic 3+3 design in three groups of up to six patients) in combination with chemotherapy across eight trial sites.
- The key endpoints were to identify the optimal dose of HER-Vaxx for the Phase 2 part of the trial and confirm safety. Researchers will monitor the patients' immune responses to the vaccine.
- The Phase 1b is being followed by a randomised open label Phase 2 trial of 68 patients with metastatic gastric cancer overexpressing HER-2. Phase 2, which commenced in February 2019, is randomised into two arms: HER-Vaxx



plus standard-of-care (chemotherapy) or standard-of-care alone. The endpoints of this randomised trial will be safety, immune response, progression-free survival and overall survival.



The Phase 1b stage of the Phase 1b/2 trial has completed with all endpoints being met. Phase 1b established safety, tolerability and the dose for the Phase 2 portion of the trial. Response rate is an exploratory endpoint in the Phase 1b trial; of the 10 patients evaluable for tumour growth assessment during the trial, five patients showed partial response (PR) and four patients showed stable disease (SD) for their best overall response.

The Phase 2 stage of the HER-Vaxx trial in HER-2 positive gastric cancer commenced in February 2019. The feasibility of adding an Indian cohort to assist in recruitment along with the other regions is currently under evaluation.

#### Ohio State University/Mayo Clinic licences

On 7 June 2018, the group announced the licencing of a substantial intellectual property estate from Ohio State University (OSU) and Mayo Clinic. This broad patent portfolio includes six patent families comprising of 16 issued patents or pending applications for compositions of matter and/or methods of use of a large range of B-cell peptide and cancer vaccines comprising PD-1, HER-1, HER-2, HER-3, VEGF, IGF-1R, CD28 peptides and combinations thereof.

The licences included a PD-1 checkpoint inhibitor B-cell vaccine for a proposed Phase 1 trial in 2019, two completed National Cancer Institute (NCI) funded, and FDA approved Phase 1 clinical trials at OSU's James Cancer Hospital and Solove Research Institute, Columbus, Ohio, and an ongoing NCI-funded, FDA approved Phase II HER-2 clinical trial at OSU.

The licence expands the group's R&D capability via access to the inventor's, Prof. Pravin Kaumaya, comprehensive translational laboratory facilities at OSU under a three-year research contract.



#### **B-Vaxx**

B-Vaxx is a B cell peptide vaccine is for the treatment of patients with HER-2 positive cancers including gastric, breast, lung, colorectal, and parotid. The Phase 1b/2 trial with B-Vaxx has completed Phase 1b. Phase 2 has since commenced, with recruitment proceeding and ongoing.

#### PD-1 B-cell peptide cancer vaccine known as 'KEY-Vaxx'

IND enabling work for the PD-1 cancer vaccine is well underway. Pre-clinical experiments and toxicology studies have commenced. Preparation for the clinical trial continues with protocol synopsis available as early as first quarter 2019.

The team has successfully completed a meeting with the FDA to discuss pre-clinical and toxicology studies as well as clinical trial design. Topics included the anticipated clinical indication, the treatment of cancers that overexpress PD-L1 including but not limited to non-small cell lung cancer (NSCLC).

#### **Enhancement of management team**

**Dr Mark Marino, MD** was appointed Imugene's Chief Medical Officer (CMO) in August 2018. Dr Marino brings deep experience to the group, having held senior level clinical development/leadership and CMO positions at top-tier pharmaceutical companies, including Daiichi-Sankyo, Hoffman-La Roche AG and Novartis Pharmaceuticals Corp.



Imugene's executive and management team (left to right): Mr Charles Walker (director), Prof. Pravin Kaumaya (SAB), Dr Anthony Good (VP Clinical Research), Ms Leslie Chong (CEO and MD), Dr Axel Hoos (director), Dr Nicholas Ede (CTO), Mr Paul Hopper (Chairman) and Dr Mark Marino (CMO)



In his previous roles, Dr Marino headed teams in oncology, cardiology, endocrinology and rare diseases where he was responsible for clinical development through to commercialisation and life cycle management.

Prior to his move into the pharmaceutical industry, Dr Marino spent seven years with the US Military's Walter Reed Army Institute of Research, the Walter Reed Army Medical Center and the Uniformed Services University of the Health Sciences.

Dr Marino holds a Medical Doctor degree from the Albert Einstein College of Medicine and a Bachelor of Science in Chemistry from the United States Military Academy.

In September and October 2018, the group strengthened its scientific leadership team by adding Tanios Bekaii-Saab, Josep Tabernero and Pravin Kaumaya to the Scientific Advisory Board (SAB) of Imagene.

Prof. Tanios Bekaii-Saab, MD is the principal investigator on numerous clinical trials focused on new targeted and immune therapies in gastrointestinal malignancies. He is co-leader of the Gastrointestinal Cancer Program at the Mayo Clinic Cancer Center, medical director of the Cancer Clinical Research Office and a senior associate consultant in the Division of Hematology/Oncology in the Department of Internal Medicine at the Mayo Clinic in Phoenix, Arizona.



Prof. Tanios Bekaii-Saab MAYO CLINIC, USA

- Professor of College of Medicine and Science
- Program Co-Leader, GI Cancer, Mayo Clinic Cancer Center
- Medical Director, Cancer Clinical Research Office (CCRO)
- Senior Associate Consultant, Mayo Clinic AZ

Prof. Bekaii-Saab is a member of the American Society of Clinical Oncology, American Association for Cancer Research and the American College of Physicians. In addition, he is co-leader of the Hepatobiliary Cancer Committee of the Alliance for Clinical Trials in Oncology Cooperative Group and the representative for the National Cancer Institute's Hepatobiliary Task Force, as well as the Southwest Oncology Group representative for the National Cancer Institute's Pancreatic Cancer Task Force.

He has authored or co-authored more than 350 peer-reviewed publications, abstracts, and book chapters in journals such as *Lancet Oncology*, *Journal of Clinical Oncology*, *JAMA*, *Journal of the National Cancer Institute*, *Annals of Oncology*, and *Clinical Cancer Research*.



Dr Joseph Tabernero, MD, PhD is the President of the European Society for Medical Oncology (ESMO), the world's leading professional organisation for medical oncology with 18,000 members representing 150 countries. In addition to his work for ESMO, Dr Tabernero is head of the Medical Oncology Department at the Vall d'Hebron Barcelona Hospital Campus, director of the Vall d'Hebron Institute of Oncology and leads the Research Innovation of Catalonia Cancer Centers Network. He directs the Barcelona-based Vall d'Hebron Institute of Oncology's gastrointestinal and endocrine tumours group and the research unit for molecular therapy of cancer.

clinical studies focused on targeted

targets.



Dr Tabernero is principal investigator of several Dr Josep Tabernero, Scientific Advisory Board member (left) with Ms Leslie Chong immunotherapies, novel chemotherapeutics and promising immune checkpoint

He serves on the editorial boards of several leading journals including *Annals of* Oncology, ESMO Open, Cancer Discovery and Clinical Cancer Research and has authored and co-authored more than 350 peer-reviewed papers.

He is a member of the American Association for Cancer Research (AACR), the American Society of Clinical Oncology (ASCO) and has been appointed as member of several international educational and scientific committees.

Prof. Pravin Kaumaya, PhD is the lead inventor of Imugene's newly licensed peptide cancer vaccine programs from OSU. He has developed multiple cancer vaccines, is a recognised world leader in cancer vaccine research and author of more than 130 peer-reviewed articles.

He is Professor of Medicine in Department of Obstetrics and Gynecology at the OSU Wexner Medical Center and the James Comprehensive Cancer Center. Prof. Kaumaya's team and medical research laboratory at OSU is focused on several translational research programs with the goal of designing and developing new immunotherapies and immunologic strategies for cancer treatment and prevention.

He is an inventor on several issued and pending patents for peptide vaccines and therapeutic technologies, an elected fellow of the American Association for the Advancement of Science (AAAS) and treasurer of the American Peptide Society.



In January 2019, Imugene appointed **Dr Michael Caligiuri** to its Scientific Advisory Board. Prof. Caligiuri is a world-renowned cancer researcher and physician whose clinical work has focused on leukemia and lymphoma.

He is the President of City of Hope National Medical Center and holds the Deana and Steve Campbell Physician-in-Chief. He was elected President of the American Association for Cancer Research (AACR) in 2017, the world's largest cancer research organisation.



Dr Michael Galigiuri CITY OF HOPE, USA

- President of City of Hope National Medical Center and holds the Deana and Steve Campbell Physicianin-Chief.
- Elected President of the American Association for Cancer Research (AACR) in 2017

Since 1990, over 100 students have trained in the Caligiuri

laboratory and have received over 200 awards for their research. Prof. Caligiuri has designed and conducted many clinical studies for over 1,500 leukemia and lymphoma patients.

Prior to his appointment at City of Hope in February of 2018, Prof. Caligiuri was CEO of OSU James Cancer Hospital (2008 to 2017) and Director of OSU's Comprehensive Cancer Center (2003 to 2017); he had been the Director of OSU's Division of Hematology-Oncology from 2000 through 2008.

Prof. Caligiuri is an elected member of the American Association for Clinical Investigation and the American Association of Physicians, and he is an elected Fellow in the American Association for the Advancement of Science (AAAS). From 2009 to 2011, he served as president of the Association for American Cancer Institutes (AACI). From 2014 to 2017 he served as the president of the Society of Natural Immunity.

In 2017, he was elected president of the American Association for Cancer Research (AACR), the world's largest cancer research organisation.

Prof. Caligiuri has served on the National Cancer Institute (NCI) Board of Scientific Counselors and Board of Scientific Advisors; he was chairman of the Institute of Medicine's National Cancer Policy Forum from 2014 to 2016. He is a chairman and/or member of 10 cancer centre advisory boards across the country.

In 2010, Prof. Caligiuri was one of four individuals in the country to receive a MERIT award from the National Cancer Institute for his work on immunity and cancer, and in 2016 he received an Outstanding Investigator Award from the National Cancer Institute. In 2018, Prof. Caligiuri was elected a Fellow of the AACR Academy.



Imugene's Scientific Advisory Board works closely with the executive and management team to maximise the potential of its therapy pipeline and rapidly progress its assets through pre-clinical and clinical proof of concept, guided by strong scientific rationale and translational science.

#### **Business strategy and prospects**

The focus of the group's operations in the short- to medium-term will be directed at the following:

The Phase 1b/2 gastric cancer study design is as follows:

- HER-Vaxx: recruitment of phase 2 trial with gastric cancer patients,
- KEY-Vaxx: accelerate pre-clinical studies; obtain an IND 'go' and to commence the clinical trial.

Ms Leslie Chong

**CEO** and Managing Director

## **Imugene Limited**

ABN 99 009 179 551

## Interim report - 31 December 2018

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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 2018 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

**Imugene Limited: Interim report** 

Imugene Limited Directors' report 31 December 2018 (continued)

Your directors present their report on the consolidated entity (referred to hereafter as the 'group') consisting of Imagene Limited and the entities it controlled at the end of, or during, the half-year ended 31 December 2018.

#### **Directors**

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

Ms Leslie Chong, Chief Executive Officer and Managing Director Mr Paul Hopper, Executive Chairman Mr Charles Walker, 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 7 of this interim financial report.

#### Significant changes in the state of affairs

There have been no significant changes in the state of affairs of the group during the period.

#### Matters subsequent to the end of the period

No matter or circumstance has arisen since 31 December 2018 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.

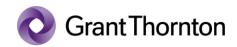
#### Rounding of amounts

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 27 February 2019



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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 2018, 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, 27 February 2019



## Financial statements

## Imugene Limited Condensed consolidated statement of profit or loss and other comprehensive income For the half-year 31 December 2018

Notes   1   1   2   2   2   2   2   2   2   2			Consolidated entity		
Notes   \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$					
Interest income			2018		
Other income         2         1,625,316         698,354           Expenses         1,817,671         719,180           Expenses         (185,091)         (117,069)           Business development         (185,091)         (117,069)           Commercialisation expenses         (82,985)         (383,250)           Corporate administration expenses         2         (28,126)         (1,153)           Foreign exchange gain/(loss)         91,912         (7,489)           Research and development expenses         (3,891,428)         (1,686,055)           Share-based payments         (343,112)         (57,624)           Finance costs         (3,449,097)         (1,632,852)           Income tax expense         (3,449,097)         (1,632,852)           Coss for the period         (3,449,097)         (1,632,852)           Other comprehensive income         (3,449,097)         (1,632,852)           Other comprehensive income for the period, net of tax         (3,449,097)         (1,632,852)           Cents         Cents         Cents    Cents  Cents  Cents  Company:  Basic loss per share for loss attributable to the ordinary equity holders of the company:  Basic loss per share		Notes	\$	\$	
Respenses   Susiness development   (185,091)   (117,069)   (200,000)   (200,	Interest income		192,355	20,826	
Expenses         (185,091)         (117,069)           Business development         (74,790)         (99,301)           Commercialisation expenses         (74,790)         (99,301)           Corporate administration expenses         (832,985)         (383,250)           Depreciation expenses         2 (28,126)         (1,153)           Foreign exchange gain/(loss)         91,912         (7,489)           Research and development expenses         (3,891,428)         (1,686,055)           Share-based payments         (343,112)         (57,624)           Finance costs         (3,148)         (91)           Loss before income tax         (3,449,097)         (1,632,852)           Income tax expense         (3,449,097)         (1,632,852)           Other comprehensive income         (3,449,097)         (1,632,852)           Other comprehensive income         (3,449,097)         (1,632,852)           Other comprehensive loss for the period         (3,449,097)         (1,632,852)           Cents         Cents         Cents	Other income	2		698,354	
Business development         (185,091)         (117,069)           Commercialisation expenses         (74,790)         (99,301)           Corporate administration expenses         (832,985)         (383,250)           Depreciation expense         2         (28,126)         (1,153)           Foreign exchange gain/(loss)         91,912         (7,489)           Research and development expenses         (3,891,428)         (1,686,055)           Share-based payments         (343,112)         (57,624)           Finance costs         (3,148)         (91)           Loss before income tax         (3,449,097)         (1,632,852)           Income tax expense         2         3,449,097)         (1,632,852)           Other comprehensive income           Other comprehensive income         3,449,097)         (1,632,852)           Cents           Cents         Cents         Cents			1,817,671	719,180	
Commercialisation expenses         (74,790)         (99,301)           Corporate administration expenses         (832,985)         (383,250)           Depreciation expense         2         (28,126)         (1,153)           Foreign exchange gain/(loss)         91,912         (7,489)           Research and development expenses         (3,891,428)         (1,686,055)           Share-based payments         (343,112)         (57,624)           Finance costs         (3,148)         (91)           Loss before income tax         (3,449,097)         (1,632,852)           Income tax expense         2         3,449,097)         (1,632,852)           Other comprehensive income         3,449,097)         (1,632,852)           Other comprehensive income for the period, net of tax         2         3,449,097)         (1,632,852)           Total comprehensive loss for the period         (3,449,097)         (1,632,852)           Loss per share for loss attributable to the ordinary equity holders of the company:         Cents           Basic loss per share         10         (0.10)         (0.07)	Expenses				
Corporate administration expenses         (832,985)         (383,250)           Depreciation expense         2         (28,126)         (1,153)           Foreign exchange gain/(loss)         91,912         (7,489)           Research and development expenses         (3,891,428)         (1,686,055)           Share-based payments         (343,112)         (57,624)           Finance costs         (3,148)         (91)           Loss before income tax         (3,449,097)         (1,632,852)           Income tax expense         -         -           Loss for the period         (3,449,097)         (1,632,852)           Other comprehensive income           Other comprehensive income for the period, net of tax         -         -         -           Total comprehensive loss for the period         (3,449,097)         (1,632,852)           Cents           Cents           Cents           Cents	·			` ' '	
Depreciation expense   2   (28,126)   (1,153)   Foreign exchange gain/(loss)   91,912   (7,489)   91,912   (7,489)   (3,891,428)   (1,686,055)   (343,112)   (57,624)   (5,263,620)   (2,351,941)   (5,263,620)   (2,351,941)   (5,263,620)   (2,351,941)   (5,263,620)   (2,351,941)   (1,632,852)					
Foreign exchange gain/(loss)         91,912 (7,489)           Research and development expenses         (3,891,428) (1,686,055)           Share-based payments         (343,112) (57,624)           Finance costs         (3,148) (91)           Loss before income tax         (3,449,097) (1,632,852)           Income tax expense            Loss for the period         (3,449,097) (1,632,852)           Other comprehensive income         (3,449,097) (1,632,852)           Other comprehensive income for the period, net of tax            Total comprehensive loss for the period         (3,449,097) (1,632,852)           Cents         Cents           Loss per share for loss attributable to the ordinary equity holders of the company:         Company:           Basic loss per share         10 (0.10) (0.10)		_			
Research and development expenses       (3,891,428)       (1,686,055)         Share-based payments       (343,112)       (57,624)         (5,263,620)       (2,351,941)         Finance costs       (3,148)       (91)         Loss before income tax       (3,449,097)       (1,632,852)         Income tax expense       -       -         Loss for the period       (3,449,097)       (1,632,852)         Other comprehensive income         Other comprehensive income for the period, net of tax       -       -         Total comprehensive loss for the period       (3,449,097)       (1,632,852)         Cents         Cents         Loss per share for loss attributable to the ordinary equity holders of the company:         Basic loss per share       10       (0.10)       (0.07)		2			
Share-based payments         (343,112) (57,624)           (5,263,620) (2,351,941)           Finance costs         (3,148) (91)           Loss before income tax         (3,449,097) (1,632,852)           Income tax expense         (3,449,097) (1,632,852)           Other comprehensive income         (3,449,097) (1,632,852)           Other comprehensive income Other comprehensive income of the period, net of tax         (3,449,097) (1,632,852)           Total comprehensive loss for the period         (3,449,097) (1,632,852)           Cents         Cents           Loss per share for loss attributable to the ordinary equity holders of the company:         (0.10) (0.07)           Basic loss per share         10 (0.10) (0.07)			,		
(5,263,620) (2,351,941)					
Cents   Cent	Snare-based payments				
Loss before income tax    (3,449,097) (1,632,852)			(5,263,620)	(2,351,941)	
Income tax expense Loss for the period  Other comprehensive income Other comprehensive income for the period, net of tax Total comprehensive loss for the period  Cents  Cents  Cents  Cents  Loss per share for loss attributable to the ordinary equity holders of the company: Basic loss per share					
Cents  Company: Basic loss per share for loss attributable to the ordinary equity holders of the company: Basic loss per share   (3,449,097) (1,632,852)  (3,449,097) (1,632,852)  Cents  Cents  Company: Basic loss per share   (0.10) (0.07)	Loss before income tax		(3,449,097)	(1,632,852)	
Other comprehensive income Other comprehensive income for the period, net of tax  Total comprehensive loss for the period  Cents  Cents  Cents  Cents  Company: Basic loss per share  10  (0.10)  (0.07)	Income tax expense		_	_	
Other comprehensive income for the period, net of tax  Total comprehensive loss for the period  Cents  Cents  Cents  Loss per share for loss attributable to the ordinary equity holders of the company: Basic loss per share  10 (0.10) (0.07)	Loss for the period		(3,449,097)	(1,632,852)	
Total comprehensive loss for the period  Cents  Cents  Cents  Loss per share for loss attributable to the ordinary equity holders of the company: Basic loss per share  10 (0.10) (0.07)					
Cents  Cents  Cents  Loss per share for loss attributable to the ordinary equity holders of the company: Basic loss per share  10 (0.10) (0.07)	·		-	- (1,000,000)	
Loss per share for loss attributable to the ordinary equity holders of the company: Basic loss per share 10 (0.10) (0.07)	Total comprehensive loss for the period		(3,449,097)	(1,632,852)	
company: Basic loss per share 10 (0.10) (0.07)			Cents	Cents	
Basic loss per share 10 <b>(0.10)</b> (0.07)					
Diluted loss per share $10$ $(0.10)$ $(0.07)$		10	(0.10)	(0.07)	
	Diluted loss per share	10	(0.10)	(0.07)	

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 2018

		Consolidat	ed entity
		31 December	30 June
	N1-4	2018	2018
	Notes	\$	\$
ASSETS			
Current assets			
Cash and cash equivalents		24,053,140	7,822,057
Trade and other receivables		1,720,102	1,914,707
Prepayments		520,822	96,207
Total current assets		26,294,064	9,832,971
Non-current assets Financial assets at amortised cost		E0 000	20,306
Property, plant and equipment	3(a)	50,000 198,225	3,898
Intangible assets	3(a)	7,057,100	7,057,100
Other non-current assets		15,593	-
Total non-current assets		7,320,918	7,081,304
			, ,
Total assets		33,614,982	16,914,275
LIABILITIES			
Current liabilities			
Trade and other payables		1,162,557	342,534
Provisions		104,807	95,706
Other current liabilities	3(b)	57,456	<u>-</u>
Total current liabilities		1,324,820	438,240
Non-company lightilities			
Non-current liabilities Provisions		20,196	15,106
Other financial liabilities		985,450	985,450
Other liabilities	3(b)	94,946	-
Total non-current liabilities	- ( )	1,100,592	1,000,556
Total liabilities		2,425,412	1,438,796
Net consts		24 490 570	15 475 470
Net assets		31,189,570	15,475,479
EQUITY			
Share capital	4(a)	63,122,435	44,285,931
Other reserves	4(b)	557,587	299,945
Accumulated losses		(32,490,452)	(29,110,397)
Total equity		31,189,570	15,475,479

#### Imugene Limited Condensed consolidated statement of changes in equity For the half-year 31 December 2018

Consolidated entity	Notes	Share capital \$	Other reserves	Accumulated losses	Total equity \$
Balance at 1 July 2017		36,335,357	1,202,024	(26,142,759)	11,394,622
Loss for the period  Total comprehensive loss for the period	-	36,335,357	1,202,024	(1,632,852) (27,775,611)	(1,632,852) <b>9,761,770</b>
Transactions with owners in their capacity as owners: Shares issued		8,731,235			8,731,235
Capital raising costs Options exercised Share-based payment expense		(755,955) 65,491	(20,491) 57,624	- - -	(755,955) 45,000 57,624
опаго-разов раутеля охропос	-	8,040,771	37,133	-	8,077,904
Balance at 31 December 2017	-	44,376,128	1,239,157	(27,775,611)	17,839,674
Balance at 1 July 2018		44,285,931	299,945	(29,110,397)	15,475,479
Loss for the period  Total comprehensive loss for the period	-	44,285,931	- 299,945	(3,449,097) (32,559,494)	(3,449,097) <b>12,026,382</b>
Transactions with owners in their capacity as owners:					
Shares issued Capital raising costs Options exercised Options forfeited/lapsed	4(a) 4(a) 4 4(b)	20,113,942 (1,443,960) 166,522	(16,428) (69,042)	- - - 69,042	20,113,942 (1,443,960) 150,094
Share-based payment expense	4(b) _	18,836,504	343,112 257,642	69,042	343,112 19,163,188
Balance at 31 December 2018	_	63,122,435	557,587	(32,490,452)	31,189,570

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 2018

	Consolidated entity		
	31 December	31 December	
	2018	2017	
	\$	\$	
Cash flows from operating activities		(0.04=.000)	
Payments to suppliers and employees	(4,644,298)	(2,047,082)	
Research and development tax incentive	1,852,597	1,130,313	
Net cash outflow from operating activities	(2,791,701)	(916,769)	
Cash flows from investing activities			
Interest received	199,303	20,826	
Payments for property, plant and equipment	(53,949)	(3,331)	
Payments for rental deposit	(15,593)	-	
Payments for term deposits	(29,694)	17.405	
Net cash inflow from investing activities	100,067	17,495	
Cash flows from financing activities	00 004 000	0.770.005	
Proceeds from issue of shares	20,264,036	8,776,235	
Capital raising costs	(1,443,960)	(773,927)	
Principal elements of lease payments	(18,900) 18,801,176	8,002,308	
Net cash inflow from financing activities	10,001,170	0,002,300	
	40 400 540	7 400 004	
Net increase in cash and cash equivalents	16,109,542	7,103,034	
Cash and cash equivalents at the beginning of the financial year	7,822,057	4,814,200	
Effects of exchange rate changes on cash and cash equivalents	121,541	6,452	
Cash and cash equivalents at end of period	24,053,140	11,923,686	

#### 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		
	<b>31 December</b> 31 Dece		
	2018	2017	
	\$	\$	
Other income			
Research and development tax incentive	1,625,316	698,354	
Expenses included in net profit/(loss) before income tax			
Depreciation charge of legally-owned assets	4,834	1,153	
Depreciation charge of right-of-use assets	23,292	-	
Superannuation	30,849	20,764	
	58,975	21,917	

#### 3 Non-financial assets and liabilities

#### (a) Property, plant and equipment

	Plant and equipment in	Leasehold nprovements	Leased plant and equipment	Total
Consolidated entity	\$	\$	\$	\$
At 31 December 2018				
Opening net book amount	3,898	-	-	3,898
Additions	7,535	46,414	168,504	222,453
Depreciation charge	(1,232)	(3,602)	(23,292)	(28,126)
Closing net book amount	10,201	42,812	145,212	198,225

#### (b) Leases

In September 2018, the group entered into a three-year commercial lease on an office in Sydney's central business district.

#### 3 Non-financial assets and liabilities (continued)

#### (b) Leases (continued)

(i) Amounts recognised in the balance sheet

	Consolidated entity		
	31 December 2018	30 June 2018	
	\$	\$	
Right-of-use assets <sup>1</sup>			
Properties	145,212	-	
	145,212		
Lease liabilities <sup>2</sup>			
Current	57,456	-	
Non-current	94,946	-	
	152,402	-	

<sup>&</sup>lt;sup>1.</sup> Included in the line item 'property, plant and equipment' in the condensed consolidated balance sheet.

#### (ii) Amounts recognised in the statement of profit or loss

	Consolidated entity		
	31 December 31 Decem		
	2018	2017	
	\$	\$	
Depreciation charge of right-of-use assets	23,292	-	
Interest expense (included in finance costs)	3,148	-	
	26,440	-	

#### (iii) The group's leasing activities and how these are accounted for

The group's lease agreement does not impose any covenants, but leased assets may not be used as security for borrowing purposes.

Leases are recognised as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use by the group. Each lease payment is allocated between the liability and finance cost. The finance cost is charged to profit or loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period. The right-of-use asset is depreciated over the shorter of the asset's useful life and the lease term on a straight-line basis.

<sup>&</sup>lt;sup>2</sup> Included in the line items 'other current liabilities' and 'other liabilities' in the condensed consolidated balance sheet.

## Imugene Limited Notes to the condensed consolidated financial statements 31 December 2018 (continued)

#### 4 Equity

	31 December 2018 No.	31 December 2018 \$	2018	30 June 2018 \$
Ordinary shares - fully paid Options	3,609,846,302 635,275,687	63,122,435 557,587	2,854,882,382 306,959,162	44,285,931 299,945
(a) Share capital				
(i) Movements in ordinary shares				
Details			Number of shares	\$
Balance at 1 July 2018			2,854,882,382	44,285,931
Issue of shares at \$0.027 each through rights issue Issue of shares at \$0.027 each to sophisticated investissue of shares at \$0.015 each by exercise of unliste Issue of shares at \$0.026 each by exercise of IMUOA Issue of shares at \$0.04 each by exercise of IMUOB Less: Transaction costs arising on share issues		300,516,177 444,444,445 10,000,000 2,675 623	8,113,942 12,000,000 166,428 69 25 (1,443,960)	
Balance at 31 December 2018			3,609,846,302	63,122,435

#### (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.

#### 4 Equity (continued)

#### (b) Other reserves

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

Details	Number of options	\$	
Balance at 1 July 2018	306,959,162	299,945	
Forfeiture of unlisted options (ESOP) at \$0.02 each Forfeiture of unlisted options (ESOP) at \$0.025 each Issue of listed options (IMUOB rights issue) Issue of listed options (IMUOB sophisticated investors) Exercise of listed options (IMUOA) at \$0.026 each Exercise of listed options (IMUOB) at \$0.04 each Exercise of unlisted options (ESOP) at \$0.015 each Issue of unlisted options (ESOP) at \$0.04 each Issue of unlisted options (ESOP) at \$0.04 each Issue of unlisted options (ESOP) at \$0.042 each Issue of unlisted options (ESOP) at \$0.045 each Amortisation of share-based payments for options issued in prior periods	(5,000,000) (5,000,000) 100,171,696 148,148,127 (2,675) (623) (10,000,000) 25,000,000 40,000,000 35,000,000	(44,456) (24,586) - - (16,428) 220,654 76,201 42,335 3,922	
Balance at 31 December 2018	635,275,687	557,587	

#### 5 Share-based payments

The following share-based payment arrangements were entered into during the half-year ended 31 December 2018 due to new options granted and vested:

Туре	Grant date	Vesting date	Expiry date	Exercise price (\$)	No. of options	Fair value (\$)
Employee options (P14-NE)	19-Jul-2018	19-Jul-2018	30-Jun-2021	0.04	5,000,000	58,357
Employee options (P14-LC)	19-Nov-2018	19-Nov-2018	30-Jun-2021	0.04	10,000,000	95,757
Employee options (P14-PH)	19-Nov-2018	19-Nov-2018	30-Jun-2021	0.04	5,000,000	47,878
Employee options (P15-NE)	19-Jul-2018	Milestone	30-Jun-2021	0.042	5,000,000	57,298
Employee options (P15-LC)	19-Nov-2018	Milestone	30-Jun-2021	0.042	20,000,000	186,679
Employee options (P15-PH)	19-Nov-2018	01-Jul-2019	30-Jun-2021	0.042	10,000,000	93,339
Employee options (P16-NE)	19-Jul-2018	Milestone	30-Jun-2021	0.045	5,000,000	55,796
Employee options (P16-LC)	19-Nov-2018	Milestone	30-Jun-2021	0.045	20,000,000	179,872
Employee options (P16-PH)	19-Nov-2018	01-Jul-2020	30-Jun-2021	0.045	10,000,000	89,936
Employee options (P17-MM)	01-Sep-2018	Milestone	31-Aug-2021	0.04	5,000,000	65,549
Employee options (P18-MM)	01-Sep-2018	Milestone	31-Aug-2021	0.042	5,000,000	63,788

#### 5 Share-based payments (continued)

For the options granted during the half-year ended 31 December 2018, the valuation model inputs used to determine the fair value at the grant date are outlined below:

Туре	Share price at grant date (\$)		Term in years	Expected volatility	Dividend yield	Risk-free	Fair value per option at grant date (\$)
P14-NE	0.022	0.04	3	105.00%	0.00%	2.14%	0.0117
P14-LC, P14-PH	0.022	0.04	3	95.00%	0.00%	2.12%	0.0096
P15-NE	0.022	0.042	3	105.00%	0.00%	2.14%	0.0115
P15-LC, P15-PH	0.022	0.042	3	95.00%	0.00%	2.12%	0.0093
P16-NE	0.022	0.045	3	105.00%	0.00%	2.14%	0.0112
P16-LC, P16-PH	0.022	0.045	3	95.00%	0.00%	2.12%	0.0090
P17-MM	0.022	0.04	3	104.00%	0.00%	2.00%	0.0131
P18-MM	0.022	0.042	3	104.00%	0.00%	2.00%	0.0128

#### (i) P14-NE, P15-NE, P16-NE

On 19 July 2018, Imugene Limited issued 15,000,000 options to a member of key management personnel, Dr Nicholas Ede. Issued in three tranches, these options either vest on grant date or on the completion of internal R&D milestones. The assessed fair value of options issued 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.

#### (ii) P14-LC, P15-LC, P16-LC

On 19 November 2018, Imugene Limited issued 50,000,000 options to Chief Executive Officer and Managing Director, Ms Leslie Chong. Issued in three tranches, these options either vest on grant date or on the completion of internal R&D milestones. The assessed fair value of options issued 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.

#### (iii) P14-PH, P15-PH, P16-PH

On 19 November 2018, Imugene Limited issued 25,000,000 options to Executive Chairman, Mr Paul Hopper. Issued in three tranches, these options either vest on grant date, 1 July 2019 or 1 July 2020. The assessed fair value of options issued 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.

#### (iv) P17-MM, P18-MM

On 1 September 2018, Imugene Limited committed to issue 10,000,000 options to a member of key management personnel, Dr Mark Marino. As at 31 December 2018 these options were not formerly issued. To be issued in two tranches, these options vest on the completion of internal R&D milestones. The assessed fair value of options issued 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.

#### 6 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) Going concern

Some of the risks inherent in the development of pharmaceutical products include the uncertainty of patent protection and proprietary rights, whether patent applications and issued patents will offer adequate protection to enable product development or may infringe intellectual property rights of other parties, and obtaining the necessary drug clinical regulatory authority approvals. Furthermore, a particular project may fail the research and the clinical development process through lack of efficacy or safety, or may be stopped or abandoned due to strategic imperatives including an assessment that the projects will not deliver a sufficient return on investment or have been superseded by newer competitive products or technologies. There is a risk that the group will be unable to find suitable development or commercial partners for its projects, and that these arrangements may not generate a material return for the group.

Based on current budget forecast assumptions, the group is in a position to meet future commitments in the current business cycle and pay its debts as and when they fall due. Furthermore, the group is able to progress its research and development programs for at least the next 12 months.

The interim financial report has been prepared on a going concern basis. Accordingly, the interim financial report does not include adjustments relating to the recoverability and classification of recorded asset amounts, or the amounts and classification of liabilities that might be necessary should the group not continue as a going concern.

#### (ii) 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 2018, the group has included an item in other income of \$1,625,316 (2017: \$698,354) to recognise this amount which relates to this period.

#### (iii) 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.

#### 7 Contingencies

On 7 June 2018, the group signed an exclusive licence with the Ohio State University and Mayo Clinic to 16 issued patents or pending applications comprising PD-1 and Non PD-1 intellectual property. Each agreement (i.e. the separate PD-1 and Non PD-1 agreements) contain the following:

- Royalties on sales: 3 percent of sales where annual turnover is less than US\$1 billion; 4 percent where annual turnover is less 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, and
- Annual licence fees: US\$250,000 per annum payable contingent on first commercial sale.

#### 7 Contingencies (continued)

The group has not recorded a liability is respect of the above due to uncertainty surrounding occurrence of these events and the consequential inability to reliably quantify a value.

#### 8 Commitments

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 related intellectual property. As at 31 December 2018, no liability was recognised on the basis that commercialised income cannot be reliably measured.

On 7 June 2018, the group signed an exclusive licence with the Ohio State University and Mayo Clinic 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 licencing 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 2018.

#### 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 31 December
2018 2017
\$ \$

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

**(3,449,097)** (1,632,852)

(b) Weighted average number of shares used as denominator

Consolidated entity
2018 2017
Number Number

Weighted average number of ordinary shares used as the denominator in calculating basic and diluted loss per share

**3,337,433,821** 2,424,462,421

#### 10 Loss per share (continued)

#### (b) Weighted average number of shares used as denominator (continued)

The outstanding options as at 31 December 2018 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 2018 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 2018 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.

AASB 9 Financial Instruments, AASB 15 Revenue from Contracts with Customers and AASB 16 Leases were early adopted in the annual report for the year ended 30 June 2018.

#### 12 Changes in accounting policies

#### (a) Leases

Leases are treated as finance leases, except short-term leases (with terms of less than 12 months) and those for low-value assets. A right-of-use asset and lease liability are recognised on the condensed consolidated balance sheet. Finance costs and depreciation of the right-of-use asset are recognised in the condensed consolidated statement of profit or loss and other comprehensive income.

In the directors' opinion:

- (a) the financial statements and notes set out on pages 8 to 24 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 2018 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 27 February 2019



Independent auditor's review report to the members



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## **Independent Auditor's Review Report**

#### To the Members of Imugene Limited

Report on the review of 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 a 31 December 2018, 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, 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 2018, 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 2018 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.

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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

Crant Thanton

T S Jackman

Partner - Audit & Assurance

Melbourne, 27 February 2019

