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Imugene Limited

Appendix 4D and

Interim report:

half-year ended

31 December 2020



IMUGENE

ABN 99 009 179 551

Imugene Limited

Appendix 4D

Half-year ended 31 December 2020

Name of entity: Imugene Limited
ABN: 99 009 179 551
Half-year ended: 31 December 2020
Previous period: 31 December 2019

Results for announcement to the market

				\$
Revenue from ordinary activities	-	-%	to	-
Loss from ordinary activities after tax attributable to members	Up	26.6%	to	6,062,737
Net loss for the period attributable to members	Up	26.6%	to	6,062,737

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 9 for explanation of the results.

This information should be read in conjunction with the 2020 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 2020.

Net tangible assets per security

	31 December 2020 Cents	31 December 2019 Cents
Net tangible asset backing (per security)	0.69	0.78

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

Changes in controlled entities

There have been no other changes in controlled entities during the half-year ended 31 December 2020.

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

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Imugene Limited
Appendix 4D
For the half-year ended 31 December 2020
(continued)

Interim review

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

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Review of Operations & Activities

Half-year ended: 31 December 2020

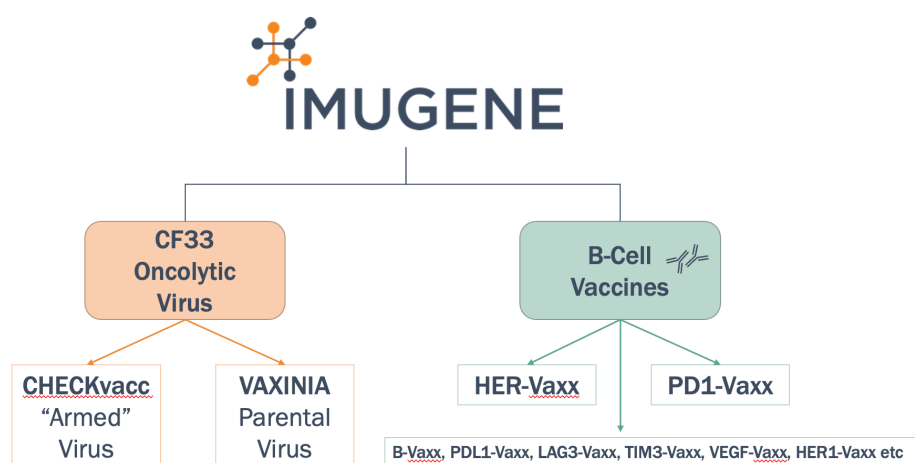
Imugene Limited is pleased to announce its financial results for the half year ended 31 December 2020.

Financial Review

The group reported a loss for the period ended 31 December 2020 of \$6,062,737 (31 December 2019: \$4,790,607). 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.

The group's net assets increased to \$63,063,057 compared with \$59,806,343 at 30 June 2020, including cash reserves of \$32,832,479 (30 June 2020: \$30,106,755).

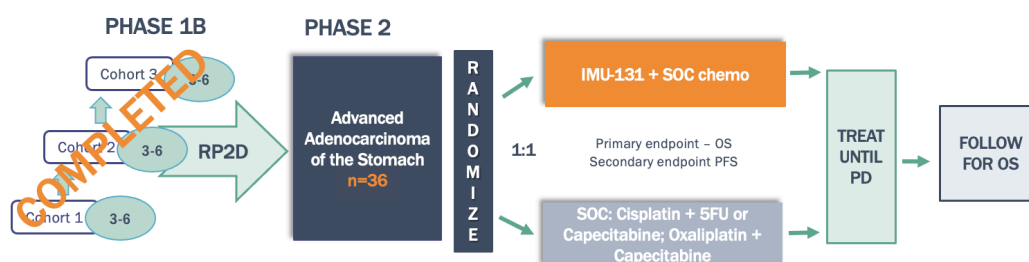
Operating Review



HER-Vaxx

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.

HER-Vaxx Phase 1B/2 Study Design



During this period, management continued to collect data and completion of HER-Vaxx Phase 2 clinical trial.

In November 2020, HER-Vaxx Phase 2 interim analysis safety and efficacy data were reviewed at the Independent Data Monitoring Committee (IDMC) meeting.

The interim analysis results from this clinical proof-of-concept study, which was designed with a specified 1-sided false positive probability of 0.10, showed twice as many patients survived on the HER-Vaxx plus SOC chemotherapy treatment arm compared to the SOC chemotherapy control arm. This translated into an overall survival HR of 0.418 (80% 2-sided CI: 0.186, 0.942) with a statistically significant 1-sided p-value of 0.083. There was no difference in safety events between the two treatment arms, suggesting that HER-Vaxx does not add toxicity to SOC chemotherapy.

The IDMC provided guidance that it is scientifically and ethically appropriate to reduce the overall number of patients required to complete the study given the strong signal observed in the data.

In summary:

- Interim analysis showed statistically significant overall survival Hazard Ratio (HR) of **0.418** (80% 2-sided CI: 0.186, 0.942); HER-Vaxx showed a reduced risk of death of **58.2%** in the HER-Vaxx plus chemotherapy group as compared to chemotherapy alone.
- The median overall survival (OS) for patients receiving HER-Vaxx plus chemotherapy was **14.2 months**, compared to **8.8 months** in patients treated with chemotherapy alone.
- The Independent Data Monitoring Committee (**IDMC**) confirms a favourable survival outcome with no added toxicity for HER-Vaxx combined with SOC chemotherapy over chemotherapy alone and advised to **reduce the overall number of patients to ~36** and number of required events **given the strong signal** that it would be considered unethical to enroll 68 as originally planned.
- The IDMC agreed, that the safety of the study is favorable with **no added toxicity** for the combination of HER-Vaxx and SOC chemotherapy versus SOC chemotherapy alone.
- The IDMC agreed that the presented data is strongly encouraging to conclude that the combination of **HER-Vaxx and SOC Chemotherapy is safe**.

- The Phase 2 data represent a **clinical proof-of-concept signal for HER-Vaxx** when added to chemotherapy and indicate that **B-cell activating immunotherapy** vaccines can induce clinically active antibody responses.

PD1-Vaxx

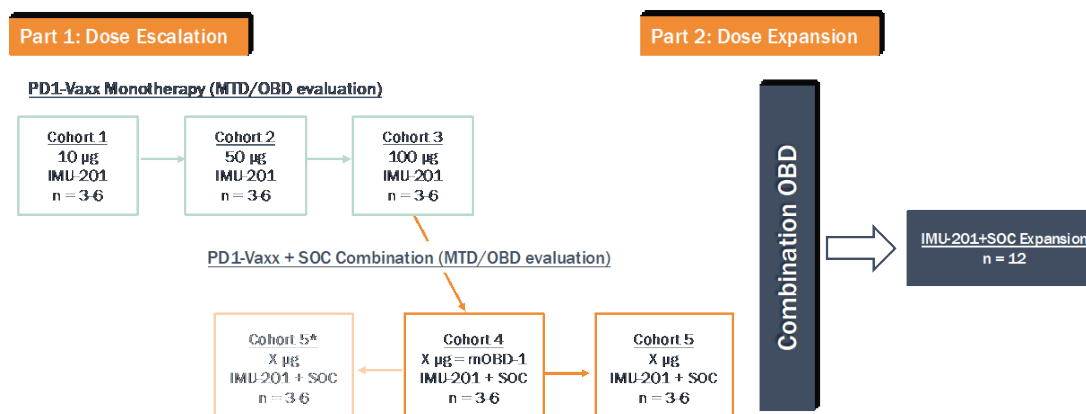
Phase 1 Non-Small Cell Lung Cancer Study

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 overexpress 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.

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

PD1-Vaxx Phase 1 Study Design



The first-in-human, Phase 1, multi-centre, dose escalation study of PD1-Vaxx is recruiting patients with non-small cell lung cancer. Medical investigators are testing three different doses of PD1-Vaxx. The primary goal of the Phase 1 trial is to determine safety and an optimal biological dose as a monotherapy (mOBD). Efficacy, tolerability and immune response will also be measured.

Clinicians running the study will determine if the administration of PD1-Vaxx as a monotherapy in patients who have progressed on standard of care immune checkpoint inhibitors will prolong survival, delay tumor progression, or reduce the tumor burden in patients with lung cancer.

Determination of mOBD is being made by the Cohort Review Committee (CRC) review and requires successive dosing within cohorts of at least 3 patients each. The CRC met today to review safety and tolerability data after the last patient in the first cohort completed 30 days of treatment. The CRC confirmed the dose in the first cohort as safe and tolerable and has approved enrolment of patients to the next higher dose level. The highest safe dose level with the best immune response becomes the mOBD.

In October 2020 three sites in Australia received Human Research Ethics Committee (HREC) approvals to commence the Phase I clinical trial. Additionally, the first Institutional Review Board approval was received in the U.S.A in New Jersey for PD1-Vaxx.

In November 2020 PD1-Vaxx received US Food and Drug Administration (FDA) Investigational New Drug (IND) approval to initiate a Phase I clinical trial of its checkpoint immunotherapy candidate.

In December 2020 the first patient was enrolled.

CF33

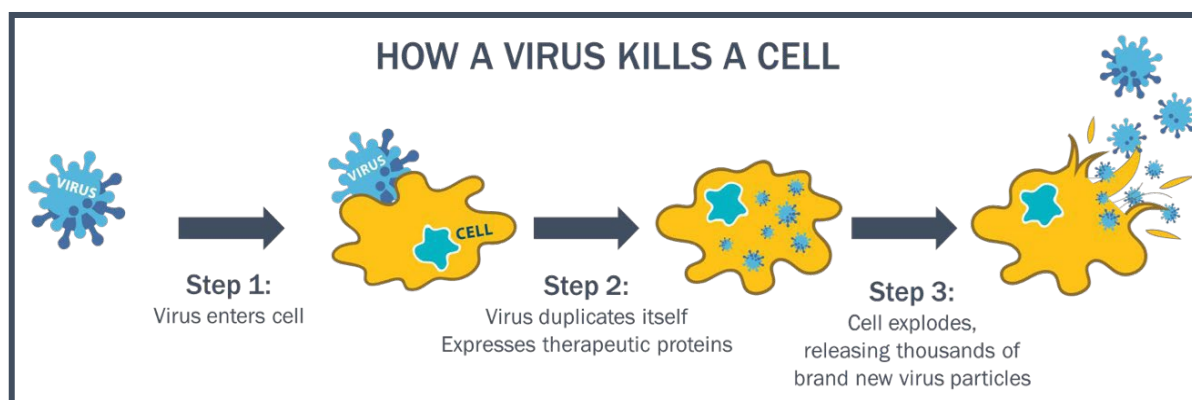
CF33 is a chimeric vaccinia poxvirus from the lab of Professor Yuman Fong, Chair of Surgery at City of Hope, and a noted expert in the oncolytic virus field.

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

CF33 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.

Pre-clinical data demonstrated that 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 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 Clinical Development

During the period, management have been working towards clinical development of CF33. CF33 has been developed in two different constructs: 'VAXinia' (CF33+hNIS) and CHECKvacc (CF33+hNIS+antiPD-L1). 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 (CF33+hNIS)

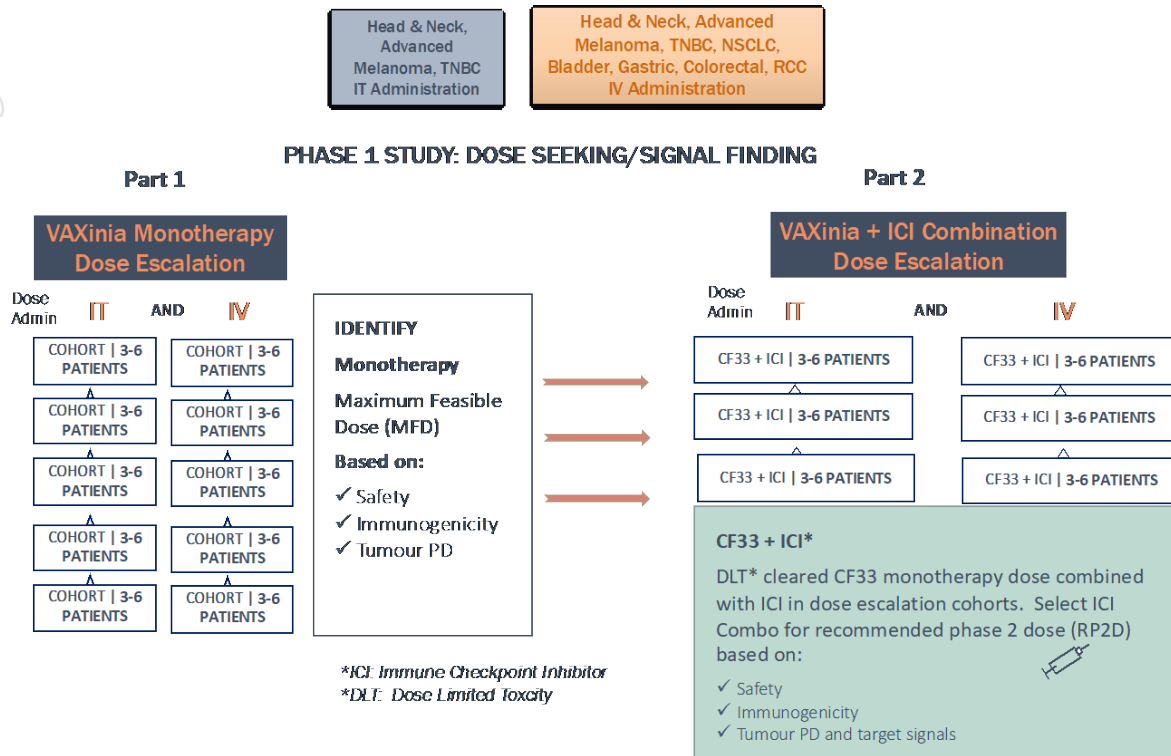
The company plans to conduct a first in human Phase 1, open-label, non-randomized, dose-escalating, multi-centre study interrogating intratumoral (IT) and intravenous (IV) administration routes of 'VAXinia' CF33+hNIS as a monotherapy and in combination with immune checkpoint inhibitors (potentially aPD-1 and aPD-L1). The potential indications may include patients with advanced melanoma, head & neck, TNBC, non-small cell lung, bladder, gastric, colorectal and renal cell carcinoma refractory to standard therapy or for which no standard therapy exists.

The primary objectives will be to determine safety and efficacy of CF33+hNIS in multiple tumour types and evaluate safety in accordance to CTCAE 5.0 criteria, establish a maximum feasible dose or recommended Phase 2 dose (RP2D) in the monotherapy with VAXinia and in combination with immune check point inhibitors and VAXinia. 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 and recommended Phase 2 dose (RP2D). The Phase 2 study could enroll up to 100 patients to evaluate therapeutic signals.

In August 2020 guidance from the U.S. FDA on development pathway for VAXinia was received. U.S. FDA guidance for CHECKvacc was previously received in early 2020. Progress for both CF33 oncolytic virotherapies, VAXINIA and CHECKvacc continues to enter into the clinic.

VAXinia PHASE 1 MAST STUDY (Mixed Advanced Solid Tumours)



CHECKvacc (CF33+hNIS+aPD-L1)

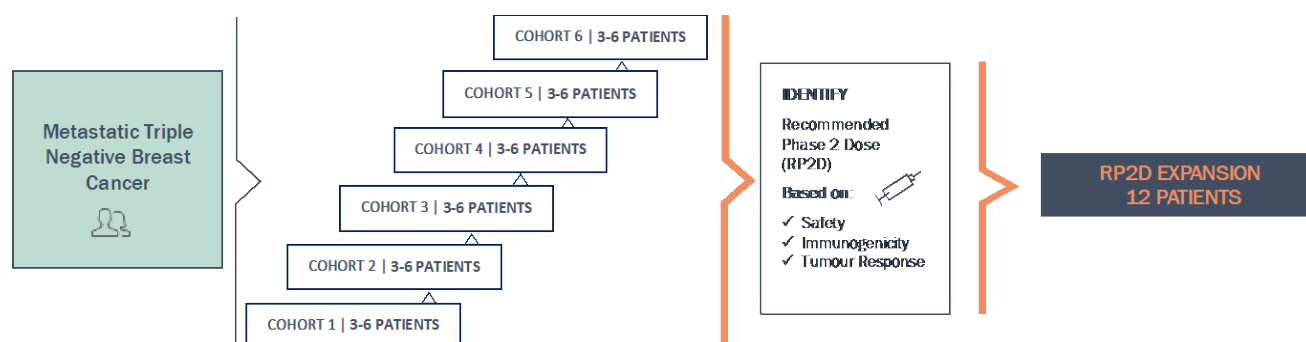
The company is also planning to conduct a first in human Phase I, open-label, non-randomized, dose-escalation, single centre study of intratumoral (IT) administration of 'CHECKvacc', CF33+hNIS+antiPD-L1, in patients with metastatic TNBC tumors refractory to standard therapy or for which no standard therapy exists and who have injectable lesions.

The primary objectives will be to determine safety and efficacy of CF33+hNIS+anti-PD-L1 against metastatic TNBC, according to CTCAE

5.0 criteria, establish a recommended dose for further Phase II testing and assess the viral kinetics of CF33+hNIS+antiPDL1 in humans. The safety of CF33-hNIS-antiPDL1 will be assessed by the evaluation of the type, frequency, and severity of adverse events (AEs), changes in clinical laboratory tests, immunogenicity, and physical examination.

The trial will involve a dose escalation, followed by an expansion to 12 subjects at the final dose (RP2D).

CHECKvacc PHASE 1 TNBC STUDY



Other Events

In September 2020 Imugene appointed Dr. Rita Laeufle to the team as the Chief Medical Officer. Dr. Laeufle will lead the Company's global clinical development, regulatory and medical monitoring activities. As a board-certified surgical oncologist and a scientist, Dr. Laeufle has extensive clinical development experience in immuno-oncology studies from Phase 1 to Phase 3 in breast and gastrointestinal cancers and registration pathways. Dr. Laeufle brings deep experience to the Company, having held senior level clinical development leadership and senior medical positions at top tier pharmaceutical companies, including Hoffman-La Roche AG, and Novartis Pharmaceuticals Corp. Most recently she was the CMO at leading oncolytic virus company Oncolytics Biotech in San Diego CA, where she will be based.

B-Cell Immunotherapy Patent

In October 2020, the patent titled "HER-1, HER-3 AND IGF-1R COMPOSITIONS AND USES THEREOF" which protects the method of composition and method of use of Imugene's Ohio State University licensed vaccines from the laboratory of Professor Pravin Kaumaya was granted. Despite the promise of targeted therapies, there remains an urgent need for effective treatment for cancers such as esophageal cancer (EC) and triple-negative breast cancer (TNBC). Current FDA-approved drugs have significant problems of toxicity, safety, selectivity, efficacy and development of resistance. The promising results protected in the patent support the rationale for dual targeting with HER-1, HER-2 and HER-3 or IGF-1R as an improved treatment regimen for advanced therapy tailored to difference types of cancer. Attaining the key US patent adds extra value to Imugene's portfolio of B-cell immunotherapies and this will protect them in the world's largest pharmaceutical market until 2035.

Events since the end of the Half Year:

On 7 January 2021, the Phase 2 trial enrolment for HER-Vaxx had been completed.

Additionally on 21 January 2021, the PD1-Vaxx clinical trial completed enrolment in the low dose cohort of patients with positive feedback from clinicians running the study. Clinicians have reported no safety, toxicity or tolerability issues with PD1-Vaxx during the first low dose cohort of patients. The CRC made the determination to dose escalate to the next highest dose in cohort 2.

For and on behalf of the company



Leslie Chong
CEO and Managing Director

Imugene Limited

ABN 99 009 179 551

Interim report - 31 December 2020

Contents

	Page
Directors' report	11
Interim financial report	
Condensed consolidated statement of profit or loss and other comprehensive income	15
Condensed consolidated balance sheet	16
Condensed consolidated statement of changes in equity	17
Condensed consolidated statement of cash flows	18
Notes to the condensed consolidated financial statements	19
Directors' declaration	29
Independent auditor's report to the members	30

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 2020 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*.

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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 2020.

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 Axel Hoos, Non-Executive Director
Dr Lesley Russell, Non-Executive Director
Dr Jens Eckstein, 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 9 of this interim financial report.

Significant changes in the state of affairs

In the opinion of the directors there were no 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 2020 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 13.

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 2021

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 2020, 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 2021



Financial statements

Imugene Limited
Condensed consolidated statement of profit or loss and other comprehensive income
For the half-year 31 December 2020

		Consolidated entity	
		31 December	31 December
		2020	2019
	Notes	\$	\$
Other income	2(a)	4,110,197	2,374,648
Other gains/(losses) – net		(10,231)	(17,421)
General and administrative expenses		(3,008,180)	(3,021,712)
Research and development expenses		(7,132,264)	(4,233,455)
Operating loss		(6,040,478)	(4,897,940)
Finance income		90,176	110,208
Finance expenses	2(b)	(112,435)	(2,875)
Finance costs - net		(22,259)	107,333
Loss before income tax		(6,062,737)	(4,790,607)
Income tax expense		-	-
Loss for the period		(6,062,737)	(4,790,607)
Other comprehensive income			
Other comprehensive income for the period, net of tax		-	-
Total comprehensive loss for the period		(6,062,737)	(4,790,607)
		Cents	Cents
Loss per share for loss attributable to the ordinary equity holders of the company:			
Basic/diluted loss per share	11	(0.13)	(0.13)

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 2020

	Consolidated entity	
	31 December	30 June
	2020	2020
Notes	\$	\$
ASSETS		
Current assets		
Cash and cash equivalents	32,832,479	30,106,755
Trade and other receivables	3(a) 3,646,131	4,193,830
Other current assets	668,971	194,059
Total current assets	37,147,581	34,494,644
Non-current assets		
Financial assets at amortised cost	80,000	80,638
Property, plant and equipment	116,782	155,624
Intangible assets	4(a) 30,458,449	30,458,449
Other assets	15,593	15,593
Total non-current assets	30,670,824	30,710,304
Total assets	67,818,405	65,204,948
LIABILITIES		
Current liabilities		
Trade and other payables	3(b) 1,906,841	1,233,272
Other financial liabilities	3(c) 1,614,222	1,434,864
Employee benefit obligations	205,477	170,412
Other current liabilities	40,467	60,934
Total current liabilities	3,767,007	2,899,482
Non-current liabilities		
Other financial liabilities	3(c) 985,450	2,488,639
Employee benefit obligations	2,891	2,082
Other non-current liabilities	-	8,402
Total non-current liabilities	988,341	2,499,123
Total liabilities	4,755,348	5,398,605
Net assets	63,063,057	59,806,343
EQUITY		
Issued capital	5(a) 101,497,239	92,797,564
Other equity	5(c) 12,097,336	12,097,336
Other reserves	5(b) 2,727,798	2,221,702
Accumulated losses	(53,259,316)	(47,310,259)
Total equity	63,063,057	59,806,343

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

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Imugene Limited
Condensed consolidated statement of changes in equity
For the half-year 31 December 2020

Consolidated entity	Notes	Share capital \$	Other equity \$	Other reserves \$	Accumulated losses \$	Total equity \$
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		22,788,650	-	-	-	22,788,650
Options issued/expensed		-	-	644,218	-	644,218
Options exercised, net of transaction costs		102,720	-	(25,038)	-	77,682
Options forfeited/lapsed		-	-	(14,455)	14,455	-
Re-valuation of options awarded in prior period		-	-	122,770	-	122,770
Acquisition of Vaxinia Pty Ltd		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
Balance at 1 July 2020		92,797,564	12,097,336	2,221,702	(47,310,259)	59,806,343
Loss for the period		-	-	-	(6,062,737)	(6,062,737)
Total comprehensive loss for the period		92,797,564	12,097,336	2,221,702	(53,372,996)	53,743,606
Transactions with owners in their capacity as owners:						
Options issued/expensed	5(b)	-	-	953,626	-	953,626
Options exercised, net of transaction costs	5(b)	8,441,572	-	(333,850)	-	8,107,722
Options forfeited/lapsed	5(b)	-	-	(113,680)	113,680	-
Issue of shares in lieu of payment of services	5(a)	114,103	-	-	-	114,103
Repayment of loaned shares to KMP		144,000	-	-	-	144,000
		<u>8,699,675</u>	<u>-</u>	<u>506,096</u>	<u>113,680</u>	<u>9,319,451</u>
Balance at 31 December 2020		101,497,239	12,097,336	2,727,798	(53,259,316)	63,063,057

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

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Imugene Limited
Condensed consolidated statement of cash flows
For the half-year 31 December 2020

		Consolidated entity	
		31 December	31 December
		2020	2019
Notes		\$	\$
Cash flows from operating activities			
	Payments to suppliers and employees (inclusive of GST)	(8,909,191)	(7,776,473)
	Research and development tax incentive received	4,848,466	4,126,678
	Net cash outflow from operating activities	<u>(4,060,725)</u>	<u>(3,649,795)</u>
Cash flows from investing activities			
	Payments for financial assets at amortised cost	-	(30,000)
	Payments for property, plant and equipment	(3,296)	(215)
	Payments for intellectual property	(1,454,539)	(1,481,672)
	Interest received	111,033	137,498
	Net cash outflow from investing activities	<u>(1,346,802)</u>	<u>(1,374,389)</u>
Cash flows from financing activities			
	Proceeds from issues of shares	5(a) 8,233,287	24,566,822
	Share issue transaction costs	(125,565)	(1,801,077)
	Principal elements of lease payments	(28,869)	(26,231)
	Proceeds from other current liabilities	-	458
	Interest paid	(1,403)	(2,875)
	Net cash inflow from financing activities	<u>8,077,450</u>	<u>22,737,097</u>
	Net increase in cash and cash equivalents	2,669,923	17,712,913
	Cash and cash equivalents at the beginning of the financial year	30,106,755	19,047,914
	Effects of exchange rate changes on cash and cash equivalents	55,801	6,176
	Cash and cash equivalents at end of period	<u>32,832,479</u>	<u>36,767,003</u>

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

(a) Other income

Loss before income tax includes the following specific items:

	Consolidated entity	
	31 December 2020	31 December 2019
	\$	\$
Other income		
Research and development tax incentive (i)	4,085,197	2,374,648
Other grants	25,000	-
	4,110,197	2,374,648

(i) Research and development tax incentive

At 31 December 2020 the group accrued \$3,395,573 (2019: \$2,374,648) in relation to the research and development spend for the current period. Additionally, Imugene received \$689,624 in relation to research and development spend that occurred in prior periods which was not previously accrued due to uncertainty around receipt of amounts. The overseas finding has been obtained and was included in the lodged application. The additional amount was received during the current period.

(b) Finance costs

	Consolidated entity	
	31 December 2020	31 December 2019
	\$	\$
<i>Finance costs</i>		
Provisions: unwinding of discount in relation to leases	(1,403)	(2,875)
Provisions: unwinding of discount in relation to acquisition costs	(111,032)	-
	(112,435)	(2,875)

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3 Financial assets and financial liabilities

(a) Trade and other receivables

	Consolidated entity					
	31 December 2020			30 June 2020		
	Current \$	Non- current \$	Total \$	Current \$	Non- current \$	Total \$
Accrued receivables	3,407,234	-	3,407,234	2,387,736	-	2,387,736
Other receivables	238,897	-	238,897	160,320	-	160,320
	3,646,131	-	3,646,131	2,548,056	-	2,548,056

(i) Accrued receivables

Accrued receivables comprise \$3,395,573 from the Australian Taxation Office in relation to the R&D tax incentive (2019: \$2,374,649) and \$11,661 interest income from deposits at call (2019: \$13,087).

(b) Trade and other payables

	Consolidated entity					
	31 December 2020			30 June 2020		
	Current \$	Non- current \$	Total \$	Current \$	Non- current \$	Total \$
Trade payables	1,812,415	-	1,812,415	1,013,039	-	1,013,039
Accrued expenses	20,500	-	20,500	216,888	-	216,888
Other payables	73,926	-	73,926	3,345	-	3,345
	1,906,841	-	1,906,841	1,233,272	-	1,233,272

(c) Other financial liabilities

	Consolidated entity					
	31 December 2020			30 June 2020		
	Current \$	Non- current \$	Total \$	Current \$	Non- current \$	Total \$
Expected future royalties payable (HER-Vaxx)	-	985,450	985,450	-	985,450	985,450
CF33 contingent consideration	1,614,222	-	1,614,222	1,434,864	1,503,189	2,938,053
	1,614,222	985,450	2,599,672	1,434,864	2,488,639	3,923,503

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4 Non-financial assets and liabilities

(a) Intangible assets

	Consolidated entity	
	31 December	30 June
	2020	2020
	\$	\$
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	23,401,349	23,401,349
	<u>30,458,449</u>	<u>30,458,449</u>

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

5 Equity

	31 December 2020 No.	31 December 2020 \$	30 June 2020 No.	30 June 2020 \$
Fully paid	4,740,920,126	101,497,239	4,425,970,549	92,797,564

(a) Share capital

(i) Movements in ordinary shares

Details	Number of shares	\$
Balance at 1 July 2020	4,425,970,549	92,797,564
Issue at \$0.026 on exercise of IMUOA options (2020-08-05 to 2020-12-01)	242,418,174	6,302,872
Issue at \$0.04 on exercise of IMUOB options (2020-08-05 to 2020-12-01)	13,585,357	543,414
Issue at \$0.02 on exercise of ESOP unlisted options (2020-08-05)	10,000,000	200,000
Issue at \$0.0125 on exercise of ESOP unlisted options (2020-08-05)	9,000,000	112,500
Issue at \$0.015 on exercise of ESOP unlisted options (2020-08-05)	9,000,000	135,000
Issue at \$0.0175 on exercise of ESOP unlisted options (2020-08-05)	9,000,000	157,500
Transfer from reserves on exercise of ESPOP unlisted options (2020-08-05)	-	178,905
Issue at \$0.054 on exercise of IMUOC options (2020-12-01)	3,000,000	162,000
Issue at \$0.029 to consultant in lieu of payment for services (2020-12-09)	3,946,046	114,103
Issue at \$0.04 on exercise of ESOP unlisted options (2020-12-16)	5,000,000	200,000
Issue at \$0.042 on exercise of ESOP unlisted options (2020-12-16)	10,000,000	420,000
Transfer from reserves on exercise of ESPOP unlisted options (2020-12-16)	-	154,945
Repayment of loaned shares to KMP	-	144,000
Less: Transaction costs arising on share issues	-	(125,564)
Balance at 31 December 2020	4,740,920,126	101,497,239

(ii) Rights of each type of share

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

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5 Equity (continued)

(b) Other reserves

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

Details	Number of options	\$
Balance at 1 July 2020	1,010,376,410	2,221,702
Exercise of IMUOA options at \$0.026 (2020-08-05)	(242,418,174)	-
Exercise of IMUOB options at \$0.04 (2020-08-05)	(13,585,357)	-
Exercise of ESOP unlisted options at \$0.02 (2020-08-05)	(10,000,000)	(78,000)
Exercise of ESOP unlisted options at \$0.0125 (2020-08-05)	(9,000,000)	(37,039)
Exercise of ESOP unlisted options at \$0.015 (2020-08-05)	(9,000,000)	(33,434)
Exercise of ESOP unlisted options at \$0.0175 (2020-08-05)	(9,000,000)	(30,432)
Exercise of IMUOC options at \$0.054 (2020-12-01)	(3,000,000)	-
Lapse of ESOP unlisted options at \$0.04 (2020-12-01)	(5,000,000)	(57,614)
Lapse of ESOP unlisted options at \$0.042 (2020-12-01)	(5,000,000)	(56,066)
Issue of ESOP unlisted options at \$0.06 each (2020-12-03)	5,000,000	45,495
Issue of ESOP unlisted options at \$0.065 each (2020-12-03)	5,000,000	25,466
Exercise of ESOP unlisted options at \$0.04 (2020-12-16)	(5,000,000)	(62,000)
Exercise of ESOP unlisted options at \$0.042 (2020-12-16)	(10,000,000)	(92,945)
Issue of ESOP unlisted options at \$0.09 each (2020-12-16)	10,000,000	561,572
Amortisation of share-based payments for options previously issued	-	321,093
Balance at 31 December 2020	709,372,879	2,727,798

(c) Other equity

	31 December 2020 \$	30 June 2020 \$
Contingent issue of equity	12,097,336	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.

6 Share-based payments

(a) Employee share option plan (ESOP)

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

The model inputs for options re-valued and granted under ESOP during the half-year 31 December 2020 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 (\$)
2020-09-30 (IMUOP24)	2023-09-30	0.065	5,000,000	0.047	92.60%	0.00%	0.17%	126,500
2020-09-30 (IMUOP25)	2023-09-30	0.060	5,000,000	0.047	92.60%	0.00%	0.17%	135,000
2020-12-01 (IMUOP26)	2023-12-01	0.090	10,000,000	0.130	90.90%	0.00%	0.12%	840,000
			<u>20,000,000</u>					

(b) Expenses arising from share-based payment transactions

At 9 December 2020, the group granted 3,946,046 shares to a consultant in lieu of services completed. The value of the shares granted was \$114,103.

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 2020, the group has included an item in other income of \$3,395,573 (2019: \$2,374,648) 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
- **Sublicencing fees:**
 - 25 percent of sublicensing consideration prior to first patient dosing in Phase I clinical trial
 - 15 percent of sublicensing consideration prior to first patient dosing in Phase II clinical trial
 - 10 percent of sublicensing consideration prior to first patient dosing in Phase III clinical trial
 - 8 percent of sublicensing consideration after first patient dosing in Phase III clinical trial

(b) CF33 intellectual property

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

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

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:

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8 Contingencies (continued)

(b) CF33 intellectual property (continued)

- **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

- **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.

(c) Share arrangement

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

At 31 December 2020 \$156,000 of the original amount represents a contingent asset, while the remaining \$144,000 is payable to Imugene.

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9 Commitments

(a) Research and development commitments

The group had research and development commitments at 31 December 2020 in respect of:

(i) 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 year ending 30 June 2021. These payments are for work yet to be performed as at 31 December 2020.

(ii) 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

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

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 Loss per share

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

Consolidated entity	
31 December	31 December
2020	2019
\$	\$

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	(6,062,737)	(4,790,607)
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(b) Weighted average number of shares used as denominator

Consolidated entity	
31 December	31 December
2020	2019
Number	Number

Weighted average number of ordinary shares used as the denominator in calculating basic and diluted loss per share	4,531,748,112	3,727,634,101
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The outstanding options as at 31 December 2020 are considered to be anti-dilutive and therefore were excluded from the diluted weighted average number of ordinary shares calculation.

12 Basis of preparation of interim report

These condensed consolidated financial statements for the half-year reporting period ended 31 December 2020 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 2020 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.

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In the directors' opinion:

- (a) the financial statements and notes set out on pages 10 to 28 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 2020 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 2021

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Independent auditor's review report to the members

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 at 31 December 2020, and the consolidated statement of profit or loss and other comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the half year ended on that date, a description of accounting policies, other selected explanatory notes, and the directors' declaration.

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

- (a) giving a true and fair view of Imugene Limited's financial position as at 31 December 2020 and of its performance for the half-year ended on that date; and
- (b) complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

Basis for Conclusion

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

Directors' responsibility for the half year financial report

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

Auditor's responsibility

Our responsibility is to express a conclusion on the half-year financial report based on our review. We conducted our review in accordance with Auditing Standard on Review Engagements ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity*, in order to state whether, on the basis of the procedures described, we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the *Corporations Act 2001* including giving a true and fair view of the Group's financial position as at 31 December 2020 and its performance for the half-year ended on that date, and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

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



Grant Thornton Audit Pty Ltd
Chartered Accountants



T S Jackman
Partner – Audit & Assurance

Melbourne, 26 February 2021



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Imugene Limited
Interim report
half-year ended
31 December 2020
IMUGENE