



26 February 2020

**HALF-YEAR FINANCIAL REPORT 31 DECEMBER 2019**

In accordance with Listing Rule 4.2A, we enclose the Half-Year Financial Report (reviewed) on the consolidated results of Opthea Limited ('Opthea' or 'Group') for the half-year ended 31 December 2019. The previous corresponding periods are the financial year ended 30 June 2019 and the half-year ended 31 December 2018.

Information in relation to the operational performance, financial performance, cash flows and financial position is included in the attached Appendix 4D Half-Year Financial Report.

This Half-Year Financial Report should be read in conjunction with the Company's Annual Report for the year ended 30 June 2019.

A handwritten signature in black ink, appearing to read "MT", followed by a horizontal line.

**Mike Tonroe**  
Company Secretary

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# APPENDIX 4D HALF-YEAR FINANCIAL REPORT

OPTHEA LIMITED  
ABN 32 006 340 567

**REPORTING PERIOD: HALF-YEAR ENDED 31 DECEMBER 2019**

**PREVIOUS CORRESPONDING PERIOD: HALF-YEAR ENDED 31 DECEMBER 2018**

## INDEX

- |   |                                    |
|---|------------------------------------|
| 1. Results for announcement to the market | next page                          |
| 2. Financial report:                      |                                    |
| - Directors' Report                       | page 1 of the financial report     |
| - Auditor's Independence Declaration      | page 5 of the financial report     |
| - Financial Statements                    | pages 6–15 of the financial report |
| - Directors' Declaration                  | page 16 of the financial report    |
| - Independent Auditor's Review Report     | page 17 of the financial report    |

This half-year report is to be read in conjunction with the Company's 2019 Annual Report

**Note:** The financial figures provided are in Australian dollars.

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## RESULTS FOR ANNOUNCEMENT TO THE MARKET

The consolidated results of Opthea Limited for the six months ended 31 December 2019 are as follows:

### Revenues and results from ordinary activities

		Change compared to:		
		31/12/2018		31/12/2019
		%		\$
Revenues from ordinary activities	Decreased	43	to	273,115
Loss from ordinary activities before tax	Loss has decreased	39	to	11,465,210
Loss from ordinary activities after tax attributable to members	Loss has decreased	32	to	7,620,018

An explanation of the figures reported above are contained in the Directors' Report under the heading 'Financial performance'.

## SHAREHOLDER DISTRIBUTIONS

No dividends have been paid or declared by the entity since the beginning of the current reporting period.

	Consolidated	
NTA backing	31/12/2019	30/06/2019
Net tangible asset backing per ordinary security	\$0.27	\$0.12

## STATUS OF REVIEW OF ACCOUNTS

The financial report for the half-year ended 31 December 2019 has been reviewed. The auditor's review report is included at page 17 of the financial report.

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OPTHEA LIMITED  
AND CONTROLLED  
ENTITIES

ABN 32 006 340 567

HALF YEAR REPORT FOR  
THE HALF-YEAR ENDED  
31 DECEMBER 2019

## CONTENTS

1	Directors' Report
5	Auditor's Independence Declaration
6	Condensed Consolidated Statement of Profit or Loss and Other Comprehensive Income for the Half-Year Ended 31 December 2019
7	Condensed Consolidated Statement of Financial Position as at 31 December 2019
8	Condensed Consolidated Statement of Changes in Equity for the Half-Year Ended 31 December 2019
9	Condensed Consolidated Statement of Cash Flows for the Half-Year Ended 31 December 2019
10	Notes to the Condensed Consolidated Financial Statements for the Half-Year Ended 31 December 2019
16	Directors' Declaration
17	Independent Auditor's Review Report

# TO IMPROVE THE VISION OF MILLIONS

# DIRECTORS' REPORT

The directors of Opthea Limited submit herewith the financial report of Opthea Limited and its subsidiaries (Opthea, the Company and the Group) for the half-year ended 31 December 2019. In order to comply with the provisions of the *Corporations Act 2001*, the directors report as follows:

## DIRECTORS

The names of the Company's Directors in office during the half-year and until the date of this report are:

Geoffrey Kempler	Chairman, Non-Executive Director
Megan Baldwin	Chief Executive Officer and Managing Director
Michael Sistenich	Non-Executive Director

## REVIEW OF OPERATIONS

### Financial performance

For the half year ended 31 December 2019, the Company's net loss before tax attributable to members is \$11,465,210 (31 December 2018: \$18,918,763). The decreased loss compared to the prior year is mainly due to the reduction in research and development (R&D) spending, which can be attributed to the completion of the Phase 2b clinical trial of OPT-302 in wet AMD.

Set out below are other factors affecting financial performance:

- / The total investment in R&D was \$8,340,640 (31 December 2018: \$17,352,777).
- / The net income tax benefit for the half year is \$3,845,192 (31 December 2018: \$7,636,944).
- / Basic earnings per share were a loss of 3.02 cents (31 December 2018: loss of 5.21 cents).

### Financial position

Points to note on the Company's financial position are:

- / The cash position as at 31 December 2019 was \$75,087,651 (30 June 2019: \$21,534,919).
- / The 2019 Research and Development (R&D) tax incentive claim of \$14,636,973 was received from the Australian Tax Office during September 2019. A benefit of \$3,845,192 (31 December 2018: \$7,636,944) has been recognised in relation to the R&D tax incentive spend in the current period and included in current tax assets.
- / During the half year to 31 December 2019, 18,867,930 new shares were issued in a placement, increasing contributed equity by \$48,722,444.
- / As at 31 December 2019, the Net Tangible Asset backing per share was 27 cents (30 June 2019: 12 cents).

## OPTHEA: COMPANY OVERVIEW

Wet (neovascular) age-related macular degeneration (wet AMD) and diabetic macular edema (DME) are the leading causes of visual impairment in the elderly and diabetic populations respectively. Globally, progressive vision loss associated with wet AMD and DME contributes to significant healthcare and economic costs and greatly impacts patient independence and quality of life.

Current treatment options for wet AMD and DME patients are limited and work sub-optimally in the majority of patients. With the prevalence of both diseases on the rise given the aging population and rising incidence of diabetes worldwide, there remains a significant market opportunity for novel therapies that can improve vision in patients with these diseases.

OPT-302 is a novel therapeutic being developed by Opthea to improve vision and reduce swelling in patients with back-of-the-eye or retinal eye diseases. The company has now completed several clinical trials to investigate safety and determine if OPT-302 improves visual acuity in patients receiving standard of care therapy for wet AMD and DME, including a first-in-human Phase 1/2a trial in wet AMD, a large Phase 2b wet AMD study and a Phase 1b clinical trial in DME. Opthea met the primary endpoint of its large, international, randomised, controlled Phase 2b clinical trial of OPT-302 in combination with Lucentis (ranibizumab) in August 2019, and expects to report outcomes from its Phase 2a trial in patients with persistent DME despite prior anti-VEGF-A therapy in 2Q CY 2020.

## DIRECTORS' REPORT (CONT.)

### WET AMD AND DME REPRESENT LARGE COMMERCIAL OPPORTUNITIES FOR NOVEL THERAPIES

Both wet AMD and DME are associated with vascular dysfunction and fluid accumulation at the back of the eye in a region of the central retina or 'macula' that is needed for sharp, central vision. Vessel growth and vascular leakage are primarily driven by members of the vascular endothelial growth factor (VEGF) family, which comprises 5 members including VEGF-A, VEGF-B, VEGF-C, VEGF-D and placenta growth factor (PlGF). Elevated levels of these signals and their receptors are associated with retinal disease progression.

Current treatments for wet AMD and DME share a common mechanism of action by inhibiting VEGF-A. VEGF-A inhibitors approved for the treatment of these diseases include Lucentis® (ranibizumab) and Eylea® (aflibercept) which together generated revenues in excess of 10 billion USD in 2019. Despite the widespread use and extraordinary commercial success of this class of therapies for retinal disease, many patients respond sub-optimally. As such, there remains a very large commercial opportunity for novel therapies that can address the unmet medical need in patients that experience sub-optimal gains in visual acuity and/or persistent retinal fluid despite regular administration of existing treatments.

### OPT-302: OPTHEA'S APPROACH TO ADDRESS THE UNMET MEDICAL NEED FOR PATIENTS WITH RETINAL DISEASE

Approved therapies for wet AMD and DME block the activity of VEGF-A, but not VEGF-C and VEGF-D which also stimulate blood vessel growth and vascular leakage and are implicated in the progression of retinal diseases. OPT-302 is a fusion protein that binds and neutralises the activity of VEGF-C and VEGF-D and is being developed by Opthea as a complementary medicine to be used in conjunction with VEGF-A inhibitors for the treatment of wet AMD and DME.

By combining administration of OPT-302 with a VEGF-A inhibitor, complete blockade of important signalling pathways that contribute to the pathophysiology of retinal diseases can be achieved, which may improve visual acuity and retinal swelling in patients. Furthermore, as both VEGF-C and VEGF-D can be upregulated to compensate for VEGF-A inhibition, OPT-302 may block mechanisms of resistance to existing therapies, which may then result in improved and more durable clinical responses.

With a scarcity of novel combination therapies in development that may offer improved outcomes for retinal disease patients, Opthea's OPT-302 is a promising drug candidate with encouraging clinical data and large commercial potential.

### OPERATIONAL UPDATE

Over the past 6 months, Opthea has continued to progress its clinical development program investigating OPT-302 as a combination therapy in two distinct retinal diseases:

- / Wet (neovascular) AMD:  
Opthea reported outcomes from its randomised, controlled Phase 2b clinical trial of 366 treatment-naive patients investigating OPT-302 administered in combination with the VEGF-A inhibitor Lucentis compared to Lucentis alone. The trial met the primary endpoint, demonstrating superior gains in visual acuity in patients receiving OPT-302 combination treatment compared to patients receiving Lucentis alone. The positive results of the trial announced in August 2019 were presented at the EURETINA congress in September 2019 and the OIS meeting in the US in October 2019.
- / Persistent, central-involved DME:  
Opthea completed recruitment of patients with persistent DME into a Phase 2a study of OPT-302 administered in combination with Eylea.

In December 2019 Opthea raised \$50 million equity capital in a placement supported by Australian and UK based institutional investors. In addition, in September 2019, Opthea received a A\$14.6 million research and development (R&D) tax credit from the Australian Taxation Office. Consequently, Opthea is fully funded through the completion of the Phase 2a clinical trial. The company also has sufficient funds to progress Phase 3 preparatory activities, including manufacture of OPT-302 and initiation activities for a Phase 3 program in wAMD.

To facilitate the progression of Opthea's clinical development program, Opthea has entered into research and development contracts with various third parties, including a global contract research organization (CRO) to provide services for the conduct of clinical trials. These activities and forecast expenditure in note 13 (page 15) were anticipated and are consistent with use-of-funds disclosures to shareholders in support of the December 2019 fundraising.

### WET AMD CLINICAL TRIAL

Opthea's Phase 2b wet AMD clinical trial was a randomized, double-masked, controlled study of OPT-302 + Lucentis compared to Lucentis alone in 366 wet AMD patients. Patients were recruited across 113 trial sites in the US, Israel and Europe (including the United Kingdom, France, Poland, Hungary, Spain, Latvia, Italy and Czech Republic).

All patients recruited to the study were newly diagnosed treatment naive patients who had not received prior therapy for wet AMD. Patients were assigned to one of three treatment groups and received either Lucentis alone, or OPT-302 (low dose, 0.5 mg) in combination with Lucentis or OPT-302 (high dose, 2.0 mg) in combination with Lucentis. Agents were administered on a monthly basis for six months via intravitreal (ocular) injection.

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The primary endpoint of the study was the assessment of visual acuity at the completion of the dosing period (week 24) compared to baseline. In addition, several secondary outcome measures were also assessed including anatomical parameters of the wet AMD lesion using imaging techniques such as optical coherence tomography and fluorescein angiography.

Patient recruitment into the trial was completed in under 12 months and a number of months ahead of projected timelines, reflecting the commitment of both patients and clinical investigators to advance promising new treatments for this debilitating disease.

On 7 August 2019 the Company announced positive results from its Phase 2b clinical trial of OPT-302. The prospective, randomized, controlled clinical trial met the pre-specified primary endpoint of superiority in mean visual acuity gain at 24 weeks compared to Lucentis monotherapy. Patients receiving the combination of OPT-302 (2.0 mg) and Lucentis gained a mean of 14.2 letters of vision on the Early Treatment of Diabetic Retinopathy Study (ETDRS) standardized eye chart at 24 weeks, compared to 10.8 letters for patients receiving Lucentis monotherapy, an improvement of 3.4 letters ( $p=0.0107$ ). Low dose OPT-302 (0.5 mg) combined with Lucentis had similar effects to Lucentis monotherapy (mean visual acuity gain of 9.4 letters at 24 weeks). In addition, OPT-302 (2.0 mg) combination therapy showed improvements across multiple secondary endpoints of functional measures in support of the primary outcome, including a higher proportion of patients with stable vision (defined as  $\leq 15$  letter loss) and also for those gaining  $\geq 10$  and  $\geq 15$  letters of visual acuity, compared to Lucentis.

OPT-302 intravitreal injections were well tolerated, with the safety profile of either dose of OPT-302 combination therapy comparable to Lucentis monotherapy. The Independent Data and Safety Monitoring Board (DSMB) confirmed that no new safety risks were identified in patients administered OPT-302 in combination with Lucentis compared to those patients administered Lucentis alone. Baseline disease and imaging characteristics were well balanced between treatment groups.

OPT-302 also showed encouraging results in multiple prospective secondary efficacy endpoints, consistent with findings from the previous first-in-human Phase 1/2a trial in wet AMD patients. 45.0% of patients receiving high dose OPT-302 + Lucentis therapy gained 15 or more letters from baseline to week 24, compared to 40.5% of patients receiving Lucentis monotherapy. The difference in the proportion of patients gaining 10 or more letters was even greater with 70% of patients gaining two or more lines of vision ( $\geq 10$  letters) in the OPT-302 (2.0 mg) combination group compared to 57.8% for Lucentis alone (an increase of 12.2%). A high proportion of patients (99.2%) achieved stable vision at week 24 in the OPT-302 (2.0 mg) combination group (defined as  $\leq 15$  letter loss from baseline) compared to 96.6% in the Lucentis monotherapy group.

Greater reductions in retinal thickness (central subfield thickness, CST), total lesion area and choroidal neovascular area was observed following OPT-302 (2.0 mg) combination therapy compared to Lucentis therapy alone. These parameters indicate structural anatomical changes in the retina, consistent with visual acuity benefits following addition of OPT-302 to standard of care treatment.

## PHASE 1B/2A DME CLINICAL TRIAL

The initiation of Opthea's Phase 1b/2a trial in patients with diabetic macular edema (DME) marked the expansion of the company's clinical development program for OPT-302 into a second ocular indication.

The primary safety objective of the Phase 1b dose escalation study of OPT-302 administered in combination with Eylea via sequential intravitreal injection on a monthly basis for three months was met in July 2018. This marked a considerable safety milestone for OPT-302, with a favourable safety profile having been demonstrated in combination with two standard of care anti-VEGF-A therapies, Lucentis (in wet AMD) and Eylea (in DME). Subsequently, in October 2018 Opthea reported positive three-month data from the 9 patients enrolled in the Phase 1b dose escalation study. Vision improvement and reductions in retinal swelling were observed following conversion to OPT-302 combination treatment in this group of patients with persistent DME, with a clear dose-response relationship of gains in visual acuity with ascending OPT-302 dose levels.

The Phase 2a randomized, controlled dose expansion trial is progressing at clinical trial sites in the US, Australia, Israel and Latvia. The target enrollment of ~140 patients was announced in January 2020, with treatment allocated in a 2:1 ratio to either OPT-302 (2 mg) with Eylea (2 mg) or Eylea (2 mg) monotherapy. The primary objectives of the Phase 2a study are to evaluate the (i) safety/tolerability and (ii) efficacy of OPT-302 by determination of clinical response rate, defined as the proportion of patients receiving combination OPT-302 and Eylea achieving a  $\geq 5$  letter gain in visual acuity (VA) at week 12 compared to baseline. Secondary outcome measures including evaluation of changes in mean VA and anatomical parameters such as central subfield thickness (CST) and retinal swelling will also be investigated.

Opthea anticipates reporting results from the DME trial by 30 June 2020.



# DIRECTORS' REPORT (CONT.)

## INTELLECTUAL PROPERTY AND INVESTOR RELATIONS

Opthea owns a patent family covering the OPT-302 molecule, and uses thereof, extending out to February 2034. This patent has been filed in 19 countries and is already granted in the United States, Australia, South Africa, Singapore, Colombia and Japan. The US patent, which granted in August 2017, includes broad claims to the OPT-302 molecule, and analogues thereof, and their use to treat disorders involving neovascularisation, including eye diseases such as wet AMD and DME.

In the United States, Opthea has two further granted patents relating to soluble VEGFR-3 molecules. The first includes composition of matter claims to soluble VEGFR-3 molecules (such as OPT-302) and extends out to November 2026. The second covers the generic use of soluble VEGFR-3 molecules (such as OPT-302) to inhibit growth of VEGFR-3 expressing blood vessels in mammalian diseases and extends out to September 2023.

Over the past 12 months, Opthea has continued to raise the profile of the company's technology to both the international and local investment community. The Company regularly presents and meets with global institutional and retail investors through investor meetings and forums. Opthea attended the 38th Annual J.P. Morgan Conference in San Francisco in January 2020. The conference attracts investors as well as pharmaceutical and biotechnology executives from around the world and is one of the industry's largest healthcare investment conferences.

Opthea presented at the European Society of Retina Specialists EURETINA 2019 Congress in Paris in September 2019, including additional analysis of the clinical data from the Phase 2b trial. The Company also presented in the Public Company Spotlight session of the Ophthalmology Innovation Summit (OIS) in San Francisco in October 2019. Opthea published first-in-human clinical data for OPT-302 in wet AMD in Ophthalmology Retina, a leading ophthalmic journal of the American Academy of Ophthalmology in October 2019.

## FUTURE DEVELOPMENTS

Opthea continues to advance the clinical development of OPT-302 to key commercial milestones by progressing patient treatment in the company's Phase 2a clinical trial with OPT-302 in persistent DME patients. Following the completion of the Phase 2b wet AMD study, Opthea is planning its Phase 3 program, including the manufacture of OPT-302 for use in the Phase 3 trials. The reporting of primary data analysis from the Phase 2a DME trial is anticipated by 30 June 2020.

The key objectives of the Company over the next 12 months are to:

### wet AMD

- / Finalise design, conduct regulatory meetings and initiate patient recruitment into the company's Phase 3 pivotal trials for wet AMD;
- / Prepare and complete the Phase 2b wet AMD clinical study report;
- / Publish outcomes of the Phase 2b wet AMD trial in a peer reviewed journal.

### Phase 2a DME

- / Complete the 3-month dosing regimen in patients enrolled in the Phase 2a DME clinical trial and complete close-out activities for the trial to facilitate primary data analysis and reporting of outcomes; and
- / Report primary data analysis of the Phase 2a clinical trial by 30 June 2020.

### Corporate:

- / Continue to ensure the global investment and pharmaceutical/biotechnology community is aware of the commercial potential inherent in OPT-302; and
- / Prepare for and strategically place Opthea for various and all opportunities to advance further development of OPT-302 through investment out-reach and engagement with pharmaceutical/biotechnology companies in the sector.

On behalf of the Directors



**Geoffrey Kempler**  
Chairman

Melbourne,  
26 February 2020

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# AUDITOR'S INDEPENDENCE DECLARATION

**Deloitte.**

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26 February 2020

The Board of Directors  
Opthea Limited  
Suite 403, Level 4  
650 Chapel Street  
SOUTH YARRA VIC 3141

Dear Board Members

**Opthea Limited**

In accordance with section 307C of the *Corporations Act 2001*, I am pleased to provide the following declaration of independence to the directors of Opthea Limited.

As lead audit partner for the review of the financial statements of Opthea Limited for the half year ended 31 December 2019, I declare that to the best of my knowledge and belief, there have been no contraventions of:

- the auditor independence requirements of the *Corporations Act 2001* in relation to the review; and
- any applicable code of professional conduct in relation to the review.

Yours faithfully

*Deloitte Touche Tohmatsu*

DELOITTE TOUCHE TOHMATSU

*Anneke du Toit*

Anneke du Toit  
Partner  
Chartered Accountants

# CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE HALF-YEAR ENDED 31 DECEMBER 2019

	Note	31 December	
		2019 \$	2018 \$
<b>Revenue</b>			
Interest revenue		268,725	388,423
Other revenue		4,390	91,915
<b>Total Revenue</b>		<b>273,115</b>	<b>480,338</b>
Other income		–	34,582
Research and development expenses		(8,340,640)	(17,352,777)
Administrative expenses		(2,416,266)	(2,073,462)
Share-based payments expense		(880,365)	(162,684)
Patent and intellectual property expenses		(203,982)	(149,768)
Occupancy expenses		(10,442)	(53,728)
Net finance income	5	113,370	358,736
<b>Loss before income tax</b>		<b>(11,465,210)</b>	<b>(18,918,763)</b>
Income tax benefit	6	3,845,192	7,636,944
<b>Loss for period</b>		<b>(7,620,018)</b>	<b>(11,281,819)</b>
<b>Other comprehensive income</b>			
<b>Items that may be subsequently reclassified to profit or loss:</b>			
Net unrealised profits/(loss) on non-current listed investments for the period		83,696	53,533
Other comprehensive profit/(loss) for the period		83,696	53,533
<b>Total comprehensive loss for the period</b>		<b>(7,536,322)</b>	<b>(11,228,286)</b>
Earnings per share for loss attributable for the ordinary equity holders of the parent:			
Basic and diluted loss per share (cents)		(3.02)	(5.21)

Notes to the financial statements are included on pages 10 to 15.

# CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION AS AT 31 DECEMBER 2019

	Note	31 December 2019 \$	30 June 2019 \$
<b>Current Assets</b>			
Cash and cash equivalents	7	75,087,651	21,534,919
Current tax receivable		3,845,192	14,636,973
Receivables		315,937	295,786
Prepayments		267,353	424,603
<b>Total current assets</b>		<b>79,516,133</b>	<b>36,892,281</b>
<b>Non-current assets</b>			
Investments in financial assets	8	314,836	714,118
Plant and equipment		46,939	54,063
Right-of-use assets	9	383,726	-
<b>Total non-current assets</b>		<b>745,501</b>	<b>768,181</b>
<b>Total assets</b>		<b>80,261,634</b>	<b>37,660,462</b>
<b>Current liabilities</b>			
Payables		5,660,263	5,951,942
Lease liabilities	10	143,616	-
Other financial liabilities		-	25,592
Provisions		576,817	538,547
<b>Total current liabilities</b>		<b>6,380,696</b>	<b>6,516,081</b>
<b>Non-current liabilities</b>			
Lease liabilities	10	242,643	-
Provisions		32,271	24,844
<b>Total non-current liabilities</b>		<b>274,914</b>	<b>24,844</b>
<b>Total liabilities</b>		<b>6,655,610</b>	<b>6,540,925</b>
<b>Net assets</b>		<b>73,606,024</b>	<b>31,119,537</b>
<b>Equity</b>			
Contributed equity	11	162,164,437	113,021,993
Accumulated losses		(93,680,078)	(86,060,060)
Reserves	12	5,121,665	4,157,604
<b>Total equity</b>		<b>73,606,024</b>	<b>31,119,537</b>

Notes to the financial statements are included on pages 10 to 15.

# CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY FOR THE HALF-YEAR ENDED 31 DECEMBER 2019

	Contributed equity \$	Options reserve \$	Share-based payments reserve \$	Unrealised gains reserve \$	Accum- ulated losses \$	Total equity \$
<b>As at 1 July 2019</b>	<b>113,021,993</b>	<b>–</b>	<b>3,420,348</b>	<b>737,255</b>	<b>(86,060,059)</b>	<b>31,119,537</b>
Other comprehensive income	–	–	–	83,696	–	83,696
Loss for the period	–	–	–	–	(7,620,018)	(7,620,018)
Total comprehensive income and expense for the period	–	–	–	83,696	(7,620,018)	(7,536,322)
Cost of share based payment	–	–	880,365	–	–	880,365
Issue of ordinary shares and exercise of LTIP options	49,142,444	–	–	–	–	49,142,444
<b>Balance as at 31 December 2019</b>	<b>162,164,437</b>	<b>–</b>	<b>4,300,713</b>	<b>820,951</b>	<b>(93,680,077)</b>	<b>73,606,024</b>
<b>As at 1 July 2018</b>	<b>98,403,149</b>	<b>1,989,067</b>	<b>2,452,838</b>	<b>477,391</b>	<b>(65,149,999)</b>	<b>38,172,446</b>
Other comprehensive income	–	–	–	53,533	–	53,533
Loss for the period	–	–	–	–	(11,281,819)	(11,281,819)
Total comprehensive income and expense for the period	–	–	–	53,533	(11,281,819)	(11,228,286)
Cost of share based payment	–	–	162,684	–	–	162,684
Issue of ordinary shares and exercise of quoted options	14,618,844	(1,989,067)	–	–	–	12,629,777
<b>Balance as at 31 December 2018</b>	<b>113,021,993</b>	<b>–</b>	<b>2,615,522</b>	<b>530,924</b>	<b>(76,431,818)</b>	<b>39,736,621</b>

Notes to the financial statements are included on pages 10 to 15.

# CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE HALF-YEAR ENDED 31 DECEMBER 2019

	31 December	
	2019 \$	2018 \$
<b>Cash flows from operating activities</b>		
Interest received	223,521	430,158
Royalty and licence income received	25,412	84,612
Grant income	–	31,282
Sales of reagents	–	3,300
Income tax refunded	14,636,973	12,017,248
Payments to suppliers, employees and for research and development and intellectual property costs (inclusive of GST)	(10,975,551)	(18,134,947)
<b>Net cash flows provided by/(used in) operating activities</b>	<b>3,910,355</b>	<b>(5,568,347)</b>
<b>Cash flows from investing activities</b>		
Proceeds from sale of investments	482,978	339,046
Purchases of plant and equipment	(4,159)	–
<b>Net cash flows provided by investing activities</b>	<b>478,819</b>	<b>339,046</b>
<b>Cash flows from financing activities</b>		
Repayment of lease liabilities	(66,664)	–
Proceeds on issue of shares	49,142,444	12,629,777
<b>Net cash flows provided by financing activities</b>	<b>49,075,780</b>	<b>12,629,777</b>
Net increase in cash and cash equivalents	53,464,954	7,400,476
Effect of foreign exchange rate changes	87,778	229,662
Cash and cash equivalents at beginning of the period	21,534,919	32,510,230
<b>Cash and cash equivalents at end of the period</b>	<b>75,087,651</b>	<b>40,140,368</b>

Notes to the financial statements are included on pages 10 to 15.

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# NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS FOR THE HALF-YEAR ENDED 31 DECEMBER 2019

## 1. CORPORATE INFORMATION

The consolidated financial report of Opthea Limited for the half-year ended 31 December 2019 was authorised for issue in accordance with a resolution of the directors on 26 February 2020.

Opthea Limited (the parent) is a company limited by shares incorporated in Australia whose shares are publicly traded on the Australian Securities Exchange (ASX).

## 2. NEW AND REVISED ACCOUNTING STANDARDS

### Amendments to Accounting Standards and new Interpretations that are mandatorily effective for the current reporting period

The Group has adopted all of the new and revised Standards and Interpretations issued by the Australian Accounting Standards Board (the AASB) that are relevant to their operations and effective for the current half-year.

New and revised Standards and amendments thereof and Interpretations effective for the current half-year that are relevant to the Group include:

- / AASB 16 Leases
- / Interpretation 23 Uncertainty over Income Tax Treatments and AASB 2017-4 Amendments to Australian Accounting Standards – Uncertainty over Income Tax Treatments

### AASB 16 Leases

In the current year, the Group has applied AASB 16 Leases which is effective for annual periods that begin on or after 1 January 2019.

AASB 16 introduces new or amended requirements with respect to lease accounting. It introduces significant changes to lessee accounting by removing the distinction between operating and finance lease and requiring the recognition of a right-of-use asset and a lease liability at commencement for all leases, except for short-term leases and leases of low value assets.

The date of initial application of AASB 16 for the Group is 1 July 2019 using a modified retrospective approach with optional practical expedients. The accounting policy for leases is set out in detail in note 3.

### Interpretation 23 Uncertainty over Income Tax Treatments

The Group has adopted Interpretation 23 for the first time in the current year. Interpretation 23 sets out how to determine the accounting tax position when there is uncertainty over income tax treatments. The Interpretation requires the Group to:

- / Determine whether uncertain tax positions are assessed separately or as a group
- / Assess whether it is probable that a tax authority will accept an uncertain tax treatment used, or proposed to be used, by an entity in its income tax filings:
  - If yes, the Group should determine its accounting tax position consistently with the tax treatment used or planned to be used in its income tax filings
  - If no, the Group should reflect the effect of uncertainty in determining its accounting tax position using either the most likely amount or the expected value method.

Adoption of Interpretation 23 has not had any material impact on the disclosures or on the amounts reported in this financial report.

## 3. SIGNIFICANT ACCOUNTING POLICIES

### Basis of preparation

This condensed consolidated financial statements have been prepared on the basis of historical cost, except for the revaluation of certain non-current assets and financial instruments. Cost is based on the fair values of the consideration given in exchange for assets. All amounts are presented in Australian dollars, unless otherwise noted.

The accounting policies and methods of computation adopted in the preparation of the half-year financial report are consistent with those adopted and disclosed in the company's 2019 annual financial report for the financial year ended 30 June 2019, except for the accounting policy on leases described below which has changed as a result of the adoption of AASB 16 Leases. The accounting policies are consistent with Australian Accounting Standards and with International Financial Reporting Standards.

### Leases

The Group assesses whether a contract is or contains a lease, at inception of the contract. The Group recognises a right-of-use asset and a corresponding lease liability with respect to all lease arrangements in which it is the lessee, except for short-term leases (defined as leases with a lease term of 12 months or less) and leases of low value assets (such as personal computers, photo copiers, small items of office furniture and telephones). For these leases, the Group recognises the lease payments as an operating expense on a straight-line basis over the term of the lease unless another systematic basis is more representative of the time pattern in which economic benefits from the leased assets are consumed.

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The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted by using the rate implicit in the lease. If this rate cannot be readily determined, the Group uses its incremental borrowing rate.

Lease payments included in the measurement of the lease liability comprise:

- / Fixed lease payments (including in-substance fixed payments), less any lease incentives receivable;
- / Variable lease payments that depend on an index or rate, initially measured using the index or rate at the commencement date;
- / The amount expected to be payable by the lessee under residual value guarantees;
- / The exercise price of purchase options, if the lessee is reasonably certain to exercise the options; and
- / Payments of penalties for terminating the lease, if the lease term reflects the exercise of an option to terminate the lease.

The lease liability is presented as a separate line in the consolidated statement of financial position.

The lease liability is subsequently measured by increasing the carrying amount to reflect interest on the lease liability (using the effective interest method) and by reducing the carrying amount to reflect the lease payments made.

The Group remeasures the lease liability (and makes a corresponding adjustment to the related right-of-use asset) whenever:

- / The lease term has changed or there is a significant event or change in circumstances resulting in a change in the assessment of exercise of a purchase option, in which case the lease liability is remeasured by discounting the revised lease payments using a revised discount rate.
- / The lease payments change due to changes in an index or rate or a change in expected payment under a guaranteed residual value, in which cases the lease liability is remeasured by discounting the revised lease payments using an unchanged discount rate (unless the lease payments change is due to a change in a floating interest rate, in which case a revised discount rate is used).
- / A lease contract is modified and the lease modification is not accounted for as a separate lease, in which case the lease liability is remeasured based on the lease term of the modified lease by discounting the revised lease payments using a revised discount rate at the effective date of the modification.

The Group did not make any such adjustments during the periods presented.

The right-of-use assets comprise the initial measurement of the corresponding lease liability, lease payments made at or before the commencement day, less any lease incentives received and any initial direct costs. They are subsequently measured at cost less accumulated depreciation and impairment losses.

Whenever the Group incurs an obligation for costs to dismantle and remove a leased asset, restore the site on which it is located or restore the underlying asset to the condition required by the terms and conditions of the lease, a provision is recognised and measured under IAS 37. To the extent that the costs relate to a right-of-use asset, the costs are included in the related right-of-use asset, unless those costs are incurred to produce inventories.

Right-of-use assets are depreciated over the shorter period of lease term and useful life of the underlying asset. If a lease transfers ownership of the underlying asset or the cost of the right-of-use asset reflects that the Group expects to exercise a purchase option, the related right-of-use asset is depreciated over the useful life of the underlying asset. The depreciation starts at the commencement date of the lease.

The right-of-use assets are presented as a separate line in the consolidated statement of financial position.

The Group applies AASB 136 to determine whether a right-of-use asset is impaired and accounts for any identified impairment loss as described in the 'Plant and equipment' policy (as outlined in the financial report for the annual reporting period).

Variable rents that do not depend on an index or rate are not included in the measurement the lease liability and the right-of-use asset. The related payments are recognised as an expense in the period in which the event or condition that triggers those payments occurs and are included in the line "Administrative expenses" in profit or loss.

As a practical expedient, AASB 16 permits a lessee not to separate non-lease components, and instead account for any lease and associated non-lease components as a single arrangement. The Group has not used this practical expedient. For a contracts that contain a lease component and one or more additional lease or non-lease components, the Group allocates the consideration in the contract to each lease component on the basis of the relative stand-alone price of the lease component and the aggregate stand-alone price of the non-lease components. Notes 9 and 10 to the financial report show details of financial impacts of the leases.

#### 4. OPERATING SEGMENTS

The consolidated entity operates mainly in one industry and one geographical segment, those being the medical technology and healthcare industry and Australia respectively. There is no seasonality or cyclical in the operations of the business.

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE HALF-YEAR ENDED 31 DECEMBER 2019 (CONT.)

## 5. NET FINANCE EXPENSE

	31 December 2019 \$	31 December 2018 \$
Net foreign exchange gains	87,778	358,736
Financial liabilities at fair value through profit or loss	25,592	–
Net finance expense	113,370	358,736

## 6. INCOME TAX

A reconciliation between tax benefit and the product of accounting loss before income tax multiplied by the Group's applicable income tax rate is as follows:

	31 December 2019 \$	31 December 2018 \$
Accounting loss before tax	(11,465,210)	(18,918,763)
At the parent entity's statutory income tax rate of 27.5%	3,152,933	5,202,660
Research and development tax credit refundable	3,845,192	7,636,944
Temporary differences and tax losses not recovered	(3,152,933)	(5,202,660)
Income tax benefit reported in the statement of comprehensive income	3,845,192	7,636,944

## 7. CASH AND CASH EQUIVALENTS

	31 December 2019 \$	30 June 2019 \$
For the purpose of the half-year statement of cash flows, cash and cash equivalents are comprised of the following:		
Cash at bank and in hand	1,587,651	1,034,919
Short term deposits	73,500,000	20,500,000
	75,087,651	21,534,919

Cash at bank earns interest at floating rates based on daily bank deposit rates.

Short term-deposits are with major Australian banks and are made for varying periods of between 30 days and 90 days, depending on the immediate cash requirements of the Group, and earn interest at a fixed rate for the respective short-term deposit periods. At period end, the average rate was 1.59% (2018 half-year: 2.67%).

## 8. NON-CURRENT ASSETS – INVESTMENTS IN FINANCIAL ASSETS

	Ownership interest		Fair value <sup>(1)</sup>		Cost of investment	
	31 Dec 2019 %	30 Jun 2019 %	31 Dec 2019 \$	30 Jun 2019 \$	31 Dec 2019 \$	30 Jun 2019 \$
<b>Listed investments</b>						
<b>Non-current investments</b>						
Antisense Therapeutics Ltd	–	1.24%	–	233,579	–	1,582,535
Optiscan Imaging Ltd	1.73%	1.76%	314,836	480,539	786,131	786,131
			<b>314,836</b>	<b>714,118</b>	<b>786,131</b>	<b>2,368,666</b>

1. The fair value represents the share (bid) price at period end, and does not include any capital gains tax or selling costs that may be applicable on the disposal of these investments.

Non-current investments in listed shares (which are not associates) are designated and accounted for as investments in financial assets pursuant to AASB 9.

## 9. RIGHT-OF-USE ASSETS

	Lease of office premises \$
<b>Cost</b>	
Additions	452,923
At 31 December 2019	452,923
<b>Accumulated depreciation</b>	
Charge for the half-year	(69,197)
At 31 December 2019	(69,197)
<b>Carrying amount</b>	
At 31 December 2019	383,726

The Group leases its main office accommodation for employees. The term of the lease is three years and is the renewal of a lease for the same premises that expired on 15 July 2019. The lease does not include the option to extend the term of the lease on expiry.

The maturity analysis of lease liabilities is presented in note 10.

	31 December 2019 \$	31 December 2018 \$
<b>Amounts recognised in profit or loss</b>		
Depreciation expense on right-of-use assets	69,197	–
Expense relating to leases of low value assets	4,835	–
	<b>74,032</b>	<b>–</b>

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE HALF-YEAR ENDED 31 DECEMBER 2019 (CONT.)

## 10. LEASE LIABILITIES

	31 December 2019 \$	30 June 2019 \$
<b>Maturity analysis:</b>		
Year 1	143,616	-
Year 2	157,560	-
Year 3	85,083	-
	<b>386,259</b>	<b>-</b>
<b>Analysed as:</b>		
Non-current	242,643	-
Current	143,616	-
	<b>386,259</b>	<b>-</b>

## 11. CONTRIBUTED EQUITY

	31 December 2019 \$	30 June 2019 \$
<b>Ordinary shares issued and fully paid</b>	162,164,437	113,021,993
Movement in ordinary shares:		
Opening balance	113,021,993	98,403,149
Issue of shares in a placement	48,722,444	-
Issue of shares on exercise of LTIP options	420,000	-
Issue of shares on exercise of options	-	12,629,777
Transfer from option reserve	-	1,989,067
	<b>162,164,437</b>	<b>113,021,993</b>
<b>Ordinary shares on issue:</b>	<b>No:</b>	<b>No:</b>
Opening balance	249,414,839	202,637,888
Issue of shares in a placement	18,867,930	-
Issue of shares on exercise of LTIP options	875,000	-
Issue of shares on exercise of options	-	46,776,951
	<b>269,157,769</b>	<b>249,414,839</b>

Issued capital at 31 December 2019 amounted to \$162,164,437 (269,157,769 fully paid ordinary shares) net of share issue costs and tax. During the half-year, the Company issued 18,867,930 ordinary shares for \$48,722,444 net of issue costs in respect of an institutional placement. The Company also issued 875,000 ordinary shares for \$420,000 in respect of the exercise of options granted to employees pursuant to the Long Term Incentive Plan.

## 12. RESERVES

	31 December 2019 \$	30 June 2019 \$
Share-based payments reserve <sup>1</sup>	4,300,714	3,420,349
Unrealised gains reserve <sup>2</sup>	820,951	737,255
Options reserve <sup>3</sup>	-	-
<b>Total reserves</b>	<b>5,121,665</b>	<b>4,157,604</b>
1. Movements in share-based payments reserve:		
Opening balance	3,420,349	2,452,838
Share-based payments expense	880,365	967,511
<b>Closing balance</b>	<b>4,300,714</b>	<b>3,420,349</b>
2. Movements in unrealised gains reserve:		
Opening balance	737,255	477,391
Unrealised gains on investments in financial assets	83,696	259,864
<b>Closing balance</b>	<b>820,951</b>	<b>737,255</b>
3. Movements in option reserve:		
Opening balance	-	1,989,067
Transfer to contributed equity: exercise of quoted options expired on 25 November 2018	-	(1,989,067)
<b>Closing balance</b>	<b>-</b>	<b>-</b>

## 13. COMMITMENTS

The Company has entered into research and development contracts with various third parties in respect of services for the Phase 2b wAMD and Phase 1b/2a DME clinical trials. Expenditure commitments relating to these and intellectual property license agreements are payable as follows:

	31 December 2019 \$	30 June 2019 \$
Within one year	4,288,359	7,776,947
After one year but not more than five years	105,170	85,446
After more than five years	128,325	128,169
	<b>4,521,854</b>	<b>7,990,562</b>

## 14. EVENTS SUBSEQUENT TO REPORTING DATE

No matters or circumstances have arisen since the end of the reporting period, not otherwise disclosed in this report, which significantly affected, or may significantly affect, the operations of the Group, the results of those operations, or the state of affairs of the Group in future financial years.

# DIRECTORS' DECLARATION

The Directors declare that:

- a. in the Directors' opinion, there are reasonable grounds to believe that the company will be able to pay its debts as and when they become due and payable; and
- b. in the Directors' opinion, the attached financial statements and notes thereto are in accordance with the *Corporations Act 2001*, including compliance with accounting standards and giving a true and fair view of the financial position and performance of the consolidated entity.

Signed in accordance with a resolution of the Directors made pursuant to s.303(5) of the *Corporations Act 2001*.

On behalf of the Directors



Geoffrey Kempler  
Chairman

Melbourne,  
26 February 2020

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# INDEPENDENT AUDITOR'S REVIEW REPORT

**Deloitte.**

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## Independent Auditor's Review Report to the members of Opthea Limited

### Report on the Half-Year Financial Report

We have reviewed the accompanying half-year financial report of Opthea Limited (the "Company") and its subsidiaries (the "Group"), which comprises the condensed consolidated statement of financial position as at 31 December 2019, and the condensed consolidated statement of profit or loss and other comprehensive income, the condensed consolidated statement of cash flows and the condensed consolidated statement of changes in equity for the half-year ended on that date, selected explanatory notes and, the directors' declaration.

#### *Directors' Responsibility for the Half-Year Financial Report*

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

#### *Auditor's Responsibility*

Our responsibility is to express a conclusion on the half-year financial report based on our review. We conducted our review in accordance with Auditing Standard on Review Engagements ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity*, in order to state whether, on the basis of the procedures described, we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the *Corporations Act 2001* including giving a true and fair view of the Group's financial position as at 31 December 2019 and its performance for the half-year ended on that date and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*. As the auditor of Opthea Limited, ASRE 2410 requires that we comply with the ethical requirements relevant to the audit of the annual financial report.

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

#### *Auditor's Independence Declaration*

In conducting our review, we have complied with the independence requirements of the *Corporations Act 2001*. We confirm that the independence declaration required by the *Corporations Act 2001*, which has been given to the directors of Opthea Limited, would be in the same terms if given to the directors as at the time of this auditor's review report.

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## INDEPENDENT AUDITOR'S REVIEW REPORT (CONT.)

**Deloitte.***Conclusion*

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

- (a) giving a true and fair view of the Group's financial position as at 31 December 2019 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*.

*Deloitte Touche Tohmatsu*

DELOITTE TOUCHE TOHMATSU



Anneke du Toit  
Partner  
Chartered Accountants  
Melbourne, 26 February 2020

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