



25 February 2019

31 December 2018 half-year financial report & operational performance

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 2018. The previous corresponding periods are the financial year ended 30 June 2018 and the half year ended 31 December 2017.

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 2018.

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

Mike Tonroe
Company Secretary



APPENDIX 4D

Half-Year Financial Report

Name of entity: **Opthea Limited**

ABN: **32 006 340 567**

Reporting period: **Half-Year Ended 31 December 2018**

Previous corresponding period: Half-Year Ended 31 December 2017

INDEX

1. Results for announcement to the market
2. Financial report:
 - Directors' report
 - Auditor's independence declaration
 - Financial statements
 - Directors' declaration
 - Independent review report

This half-year report is to be read in conjunction with the Company's 2018 Annual Report

Note: The financial figures provided are in Australian dollars.

Results for announcement to the market

The consolidated results of Opthea Limited for the six months ended 31 December 2018 are as follows:

Revenues and results from ordinary activities

		Change compared to:		
		31/12/2017		31/12/2018
		%		\$
Revenues from ordinary activities	decreased	20	to	480,338
Loss from ordinary activities before tax	Loss has increased	42	to	18,918,763
Loss from ordinary activities after tax attributable to members	Loss has decreased	1	to	11,281,819

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.

NTA backing	Consolidated	
	31/12/2018	30/06/2018
Net tangible asset backing per ordinary security	\$0.16	\$0.19

Status of review of accounts

The financial report for the half-year ended 31 December 2018 has been reviewed. The review report is included with the financial report.



Opthea Limited and controlled entities

ABN 32 006 340 567

**Condensed Financial Report
Half year ended 31 December 2018**

Contents

Directors' report	4
Auditor's independence declaration	10
Condensed consolidated statement of profit or loss and other comprehensive income	11
Condensed consolidated statement of financial position	12
Condensed consolidated statement of changes in equity	13
Condensed consolidated statement of cash flows	14
Notes to the condensed consolidated financial statements	15
Directors' declaration	21
Independent auditor's review report	22

Opthea Limited and Controlled Entities

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 2018. 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 2018, the Company's net loss before tax attributable to members is \$18,918,763 (31 December 2017: \$13,294,524). The increased loss compared to the prior year is mainly due to the increase in research and development (R&D) spending, which can be attributed to the expenditure incurred in progressing Opthea's ongoing clinical trials with OPT-302 in wet AMD and DME patients.

Set out below are other factors affecting financial performance:

- The total investment in R&D was \$17,352,777 (31 December 2017: \$10,674,904).
- The net income tax benefit for the half year is \$7,636,944 (31 December 2017: \$1,862,588).
- Basic earnings per share were a loss of 5.21 cents (31 December 2017: loss of 5.70 cents).

Financial position

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

- The cash position as at 31 December 2018 was \$40,140,368 (30 June 2018: \$32,510,230).
- The 2018 Research and Development (R&D) tax incentive claim of \$12,017,248 was received from the Australian Tax Office during October 2018. A benefit of \$7,636,944 (31 December 2017: \$1,862,588) 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 2018, 46,776,951 quoted options were exercised, increasing contributed equity by \$14,618,844 (30 June 2018: \$287,150).
- As at 31 December 2018, the Net Tangible Asset backing per share was 16 cents (30 June 2018: 19 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 retinal swelling in patients with eye diseases that affect the back-of-the-eye or retina. This lead therapeutic candidate is currently being investigated in two large Phase 2 clinical trials to determine if OPT-302 improves visual acuity in patients receiving standard of care therapy for wet AMD and DME. Opthea has made significant advances in the progress of these studies over the past 12 months and anticipates reporting outcomes from these trials by the end of calendar year 2019.

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 (afibercept) which together generated revenues in excess of 9 billion USD in 2018. 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 signaling 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 early stage 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 completed enrollment of 366 treatment-naïve patients into a randomised, controlled Phase 2b clinical trial investigating OPT-302 administered in combination with the VEGF-A inhibitor Lucentis compared to Lucentis alone.
- **Persistent, central-involved DME:**
Opthea reported outcomes from a Phase 1b dose-escalation study of OPT-302 administered in combination with Eylea and initiated patient recruitment in a ~108 patient Phase 2a trial in persistent DME.

In April 2017, following release of data from the Company's first-in-human Phase 1/2a clinical trial of OPT-302 in wet AMD, Opthea successfully raised \$45m in an oversubscribed fundraising supported by global healthcare institutional investors. In addition, in October 2018, Opthea received a A\$12.0 million research and development (R&D) tax credit from the Australian Taxation Office and proceeds of A\$13.3m through the exercise of quoted options issued in November 2014. Consequently, Opthea is fully funded through several clinical milestones, including the completion of the Phase 2b wet AMD and Phase 1b/2a DME clinical trials.

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 11 (page 20) were anticipated and are consistent with use-of-funds disclosures to shareholders in support of the April 2017 fundraising.

Phase 2b wet AMD clinical trial

Opthea's Phase 2b wet AMD clinical trial is a randomized, double-masked, controlled study investigating 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 naïve patients who have not received prior therapy for wet AMD. Patients are assigned to one of three treatment groups and receive 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 are administered on a monthly basis for six months via intravitreal (ocular) injection.

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

This Phase 2b study is now well advanced, with several patients having completed the 6 month dosing period. The company is now focused on the completion of dosing in all patients and various close-out activities, including site and data monitoring and preparatory activities for data analysis.

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. Opthea will report outcomes from the trial in the fourth quarter of calendar year 2019 (4Q'19).

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 favorable 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.

Recruitment into the Phase 2a randomized, controlled dose expansion trial is progressing, with clinical trial sites now open in the US, Australia, Israel and Latvia. Target enrollment for this trial is ~108 patients, 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 ≥ 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 currently anticipates reporting results from the DME trial before the end of calendar 2019, subject to ongoing patient recruitment.

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 more recently in 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. In November 2018, Opthea hosted a symposium in New York in which internationally recognized key opinion leaders in ophthalmology presented an update on the company's clinical development program and next generation treatments for wet AMD and DME. In addition, Opthea attended the 37th Annual J.P. Morgan Conference in San Francisco in January 2019. 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.

Several presentations were also made to the clinical ophthalmology community, with Opthea being invited to present at the Ophthalmology Innovation Summit (OIS) associated with the American Academy of Ophthalmology meeting in Chicago. An update on Opthea's wet AMD and DME clinical trial results was

also made recently in February 2019 at the Bascom Palmer Angiogenesis meeting in Miami. Further data presentations are planned over the next 12 months.

Outlook

Opthea continues to advance the clinical development of OPT-302 to key commercial milestones by progressing patient recruitment into the company's Phase 2a clinical trial with OPT-302 in persistent DME patients, as well as the completion of dosing in patients enrolled in the Phase 2b wet AMD study. The reporting of primary data analysis from both Phase 2 trials is currently anticipated by the end of calendar 2019, subject to ongoing recruitment.

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

Phase 2b wet AMD trial:

- Complete the 6-month dosing regimen in all patients enrolled in the Phase 2b wet AMD clinical trial and complete close-out activities for the trial to facilitate primary data analysis and reporting of outcomes;
- Report primary data analysis of the Phase 2b clinical trial in 4Q CY 2019;
- Prepare and complete the Phase 2b wet AMD clinical study report; and
- Publish outcomes of the Phase 2b wet AMD trial in a peer reviewed journal.

Phase 2a DME trial:

- Complete patient enrolment in the US, Australia, Israel and Latvia for the Phase 2a clinical trial in DME patients;
- 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;
- Report primary data analysis of the Phase 2a clinical trial by the end of CY 2019.

Corporate:

- Ensure the global investment and pharmaceutical/biotechnology community is aware of the commercial potential inherent in OPT-302 pre- and post- release of Phase 2 clinical trial data;
- With the goal of optimising shareholder value, 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.

Significant events after balance date

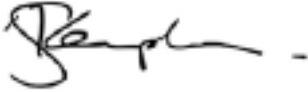
There were no significant events after 31 December 2018 to report.

Auditor's independence declaration

The Directors have obtained a declaration of independence from Deloitte Touche Tohmatsu, the Company's auditor, which is attached to this report.

Signed in accordance with a resolution of directors made pursuant to s.306 (3) of the Corporations Act 2001.

For and on behalf of the Board:



Geoffrey Kempler
Chairman
Melbourne
25 February 2019



Deloitte Touche Tohmatsu
ABN. 74 490 121 060

550 Bourke Street
Melbourne VIC 3000
GPO Box 78
Melbourne VIC 3001 Australia

Tel: +61 (0) 3 9671 7000
Fax: +61 (0) 3 9671 7001
www.deloitte.com.au

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

25 February 2019

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 2018, 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

Samuel Vorwerg
Partner
Chartered Accountants

Condensed consolidated statement of profit or loss and other comprehensive income for the half-year ended 31 December 2018

	31 December	
	2018	2017
Note	\$	\$
Revenue		
Interest revenue	388,423	554,513
Other revenue	91,915	49,420
Total Revenue	480,338	603,933
Other income	34,582	-
Research and development expenses	(17,352,777)	(10,674,904)
Administrative expenses	(2,236,146)	(2,571,384)
Patent and intellectual property expenses	(149,768)	(139,817)
Occupancy expenses	(53,728)	(51,894)
Net finance income/(expense)	4 358,736	(460,458)
Loss before income tax	(18,918,763)	(13,294,524)
Income tax benefit	5 7,636,944	1,862,588
Loss for period	(11,281,819)	(11,431,936)
Other comprehensive income		
Items that may be subsequently reclassified to profit or loss:		
Net unrealised profits/(loss) on non-current listed investments for the period	53,533	(75,145)
Other comprehensive profit/(loss) for the period	53,533	(75,145)
Total comprehensive loss for the period	(11,228,286)	(11,507,081)
Earnings per share for loss attributable for the ordinary equity holders of the parent:		
Basic and diluted loss per share (cents)	(5.21)	(5.70)

Notes to the financial statements are included on pages 14 to 19.

Condensed consolidated statement of financial position as at 31 December 2018

		31 December 2018	30 June 2018
	Note	\$	\$
Current Assets			
Cash and cash equivalents	6	40,140,368	32,510,230
Current tax assets		7,636,944	12,017,248
Receivables		447,708	393,732
Prepayments		211,327	292,257
Total Current Assets		48,436,347	45,213,467
Non-current Assets			
Investments in financial assets	7	507,788	793,301
Plant and equipment		53,040	69,086
Total Non-current Assets		560,828	862,387
Total Assets		48,997,175	46,075,854
Current Liabilities			
Payables		8,764,309	7,275,505
Provisions		477,685	459,432
Financial liabilities	8	-	129,074
Total Current Liabilities		9,241,994	7,864,011
Non-current Liabilities			
Provisions		18,560	38,462
Other liabilities		-	935
Total Non-current Liabilities		18,560	39,397
Total Liabilities		9,260,554	7,903,408
Net Assets		39,736,621	38,172,446
Equity			
Contributed equity	9	113,021,993	98,403,149
Accumulated losses		(76,431,818)	(65,149,999)
Reserves	10	3,146,446	4,919,296
Total Equity		39,736,621	38,172,446

Notes to the financial statements are included on pages 14 to 19.

Condensed consolidated statement of changes in equity for the half-year ended 31 December 2018

	Contributed equity \$	Options reserve \$	Share-based payments reserve \$	Unrealised gains reserve \$	Accumulated losses \$	Total equity \$
As at 1 July 2018	98,403,149	1,989,067	2,452,838	477,391	(65,149,999)	38,172,446
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
Balance as at 31 December 2018	113,021,993	-	2,615,522	530,924	(76,431,818)	39,736,621
As at 1 July 2017	97,853,499	1,989,067	2,064,831	832,326	(48,247,759)	54,491,964
Other comprehensive income	-	-	-	(75,145)	-	(75,145)
Loss for the period	-	-	-	-	(11,431,936)	(11,431,936)
Total comprehensive income and expense for the period	-	-	-	(75,145)	(11,431,936)	(11,507,081)
Cost of share based payment	-	-	252,807	-	-	252,807
Issue of ordinary shares	284,721	-	-	-	-	284,721
Balance as at 31 December 2017	98,138,220	1,989,067	2,317,638	757,181	(59,679,695)	43,522,411

Notes to the financial statements are included on pages 14 to 19.

Condensed consolidated statement of cash flows for the half-year ended 31 December 2018

	31 December	
	2018	2017
	\$	\$
Cash flows from operating activities		
Interest received	430,158	596,248
Royalty and licence income received	84,612	42,117
Grant income	31,282	-
Sales of reagents	3,300	-
Income tax refunded	12,017,248	-
Payments to suppliers, employees and for research and development and intellectual property costs (inclusive of GST)	(18,134,947)	(10,854,864)
Net cash flows used in operating activities	(5,568,347)	(10,216,499)
Cash flows from investing activities		
Proceeds from sale of investments	339,046	-
Purchase of plant and equipment	-	(26,797)
Net cash flows (used in) / provided by investing activities	339,046	(26,797)
Cash flows from financing activities		
Proceeds from issues of ordinary shares	12,629,777	284,721
Net cash flows provided by financing activities	12,629,777	284,721
Net increase/(decrease) in cash and cash equivalents	7,400,476	(9,958,575)
Net foreign exchange differences	229,662	(62,002)
Cash and cash equivalents at beginning of the period	32,510,230	51,959,906
Cash and cash equivalents at end of the period	40,140,368	41,939,329

Notes to the financial statements are included on pages 14 to 19.

Notes to the condensed consolidated financial statements For the half-year ended 31 December 2018

1. Corporate information

The consolidated financial report of Opthea Limited for the half-year ended 31 December 2018 was authorised for issue in accordance with a resolution of the directors on 25 February 2019.

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. Basis of preparation and accounting policies

(a) Basis of preparation

This condensed consolidated financial report has been prepared in accordance with AASB 134 Interim Financial Reporting and the Corporations Act 2001. The half-year financial report has been prepared on a historical cost basis, except for investments classified as available-for-sale, which are carried at fair value.

The half-year financial report does not include all notes of the type normally included within the annual financial report and therefore cannot be expected to provide as full an understanding of the financial performance, financial position and financing and investing activities of the consolidated entity as the full financial report.

It is recommended that the half-year financial report be read in conjunction with the annual financial report for the year ended 30 June 2018 and considered together with any public announcements made by Opthea Limited during the half-year ended 31 December 2018 in accordance with the continuous disclosure obligations of the ASX listing rules.

The financial report is presented in Australian dollars.

(b) Changes in accounting policy

The accounting policies and methods of computation are consistent with those which have been adopted in the most recent annual financial report, except for the impact of the New Standards and Interpretations as set out in note 2(c) below. These accounting policies are consistent with Australian Accounting Standards and International Financial Reporting Standards.

(c) New accounting standards and interpretations

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 an accounting period that begins on or after 1 January 2018.

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

- AASB 9 Financial Instruments and related amending Standards;
- AASB 15 Revenue from Contracts with Customers and related amending Standards;
- AASB 2016-5 Amendments to Australian Accounting Standards – Classification and Measurement of Share-based Payment Transactions;
- AASB 2017-1 Amendments to Australian Accounting Standards – Transfers of Investment; Property, Annual Improvements 2014-2016 Cycle and Other Amendments;

- Interpretation 22 Foreign Currency Transactions and Advance Consideration AASB 1048 Interpretation of Standards;
- AASB 2017-2 Amendments to Australian Accounting Standards – Further Annual Improvements 2014-2016.

Impact of the application of AASB 9 Financial Instruments and related amending Standards:

In the current year, the Group has applied AASB 9 Financial Instruments and related amending Standards which is effective for an annual period that begins on or after 1 January 2018.

At 31 December 2018, the Group had equity investments designated as available-for-sale financial assets with a fair value of \$507,788 (30 June 2018: \$793,301) that are held for long-term strategic purposes.

These investments continue to be held for the same purpose at initial application of AASB 9, the Group has elected to designate them as fair value through other comprehensive income (FVOCI).

The Group has taken advantage of the exemption allowing it not to restate comparative information for prior periods with respect to classification and measurement (including impairment) changes. There were no differences in the carrying amounts of financial assets and financial liabilities resulting from the adoption of AASB 9 recognised in retained earnings and reserves as at 1 July 2018.

Impact of the application of AASB 15 Revenue from Contracts with Customers and related amending Standards

In the current year, the Group has applied AASB 15 Revenue from Contracts with Customers (as amended) which is effective for an annual period that begins on or after 1 January 2018.

The Group earned royalties and licence fees of \$91,915 (2017: \$49,420) from its intellectual property portfolio during the year. The amount disclosed in the accounts has not been materially affected by applying AASB 15 in the 2019 financial year.

Impact of the application of AASB 2016-5 Amendments to Australian Accounting Standards – Classification and Measurement of Share-based Payment Transactions

The Group has applied these amendments for the first time in the current year. The amendments clarify the following:

1. In estimating the fair value of a cash-settled share-based payment, the accounting for the effects of vesting and non-vesting conditions should follow the same approach as for equity-settled share-based payments
2. Where tax law or regulation requires an entity to withhold a specified number of equity instruments equal to the monetary value of the employee's tax obligation to meet the employee's tax liability which is then remitted to the tax authority, i.e. the share-based payment arrangement has a 'net settlement feature', such an arrangement should be classified as equity-settled in its entirety, provided that the share-based payment would have been classified as equity-settled had it not included the net settlement feature
3. A modification of a share-based payment that changes the transaction from cash-settled to equity-settled should be accounted for as follows:
 - The original liability is derecognised
 - The equity-settled share-based payment is recognised at the modification date fair value of the equity instrument granted to the extent that services have been rendered up to the modification date
 - Any difference between the carrying amount of the liability at the modification date and the amount recognised in equity should be recognised in profit or loss immediately.

The application of these amendments has had no impact on the Group's consolidated financial statements.

Impact of the application of AASB 2017-1 Amendments to Australian Accounting Standards – Transfers of Investment; Property, Annual Improvements 2014-2016 Cycle and Other Amendments

The application of these amendments has had no impact on the Group's consolidated financial statements.

Impact of the application of Interpretation 22 Foreign Currency Transactions and Advance Consideration AASB 1048 Interpretation of Standards

Interpretation 22 addresses how to determine the 'date of transaction' for the purpose of determining the exchange rate to use on initial recognition of an asset, expense or income, when consideration for that item has been paid or received in advance in a foreign currency which resulted in the recognition of a non-monetary asset or non-monetary liability (e.g. a non-refundable deposit or deferred revenue).

The Interpretation specifies that the date of transaction is the date on which the entity initially recognises the non-monetary asset or non-monetary liability arising from the payment or receipt of advance consideration. If there are multiple payments or receipts in advance, the Interpretation requires an entity to determine the date of transaction for each payment or receipt of advance consideration.

The application of these amendments has had no effect on the Group's consolidated financial statements.

Impact of the application of AASB 2017-2 Amendments to Australian Accounting Standards – Further Annual Improvements 2014-2016

The application of these amendments has had no effect on the Group's consolidated financial statements.

New and revised Australian Accounting Standards and Interpretations on issue but not yet effective

At the date of authorisation of the financial statements, the Group has not applied AASB 16 Leases, a new Australian Accounting Standard issued and effective for annual reporting periods beginning on or after 1 January 2019. AASB 16 provides a comprehensive model for the identification of lease arrangements and their treatment in the financial statements. AASB 16 will supersede the current lease guidance including AASB 117 Leases and the related Interpretations when it becomes effective for accounting periods beginning on or after 1 January 2019. The date of initial application of AASB 16 for the Group will be 1 July 2019.

3. Segment information

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 cyclicity in the operations of the business.

4. Net finance expense

	31 December 2018	31 December 2017
	\$	\$
Net foreign exchange gains/(losses)	358,736	(62,002)
Financial liabilities at fair value through profit or loss	-	(398,456)
Net finance expense	358,736	(460,458)

5. 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 2018	31 December 2017
	\$	\$
Accounting loss before tax	(18,918,763)	(13,294,524)
At the parent entity's statutory income tax rate of 27.5%	5,202,660	3,655,994
Research and development tax credit refundable	7,636,944	1,862,588
Temporary differences and tax losses not recovered	(5,202,660)	(3,432,091)
Adjustments recognised in current year in relation to the current tax of prior period	-	(223,903)
Income tax benefit reported in the statement of comprehensive income	7,636,944	1,862,588

6. Cash and cash equivalents

	31 December 2018	30 June 2018
	\$	\$
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	1,640,368	3,010,230
Short term deposits	38,500,000	29,500,000
	40,140,368	32,510,230

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 2.67% (2017 half-year: 2.47%).

7. Non-current assets – Investments in financial assets

	Ownership interest		Fair value ⁽¹⁾		Cost of investment	
	31 Dec 2018	30 Jun 2018	31 Dec 2018	30 Jun 2018	31 Dec 2018	30 Jun 2018
	%	%	\$	\$	\$	\$
Listed investments						
Non-current investments						
Antisense Therapeutics Ltd	1.40	2.74	134,956	254,766	1,582,535	3,106,944
Optiscan Imaging Ltd	1.91	1.92	372,831	538,535	786,131	786,131
			507,788	793,301	2,368,666	3,893,075

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 available-for-sale financial assets pursuant to AASB 9.

8. Financial liabilities

	31 December 2018	30 June 2018
	\$	\$
Financial liabilities at fair value through profit or loss	-	129,074

During the period the Company used forward foreign exchange contracts (FECs) with two major Australian banks. This was for the sole purpose of reducing the risk of currency fluctuation during the term of US dollar supplier contracts for the delivery of services in respect of the Company's ongoing clinical trials in wAMD and DME. All FECs outstanding at 30 June 2018 had expired at 31 December 2018.

9. Contributed equity

	31 December 2018	30 June 2018
	\$	\$
Ordinary shares issued and fully paid		
Movement in ordinary shares:		
Opening balance	98,403,149	97,853,499
Issue of shares	12,629,777	549,650
Transfer from option reserve	1,989,067	-
	113,021,993	98,403,149
Ordinary shares on issue:	No:	No:
Opening balance	202,637,888	200,574,370
Issue of shares on exercise of options	46,776,951	2,063,518
	249,414,839	202,637,888

Issued capital at 31 December 2018 amounted to \$113,021,993 (249,414,839 fully paid ordinary shares) net of share issue costs and tax. During the half-year, the Company issued 46,776,951 ordinary shares for \$12,629,777 in respect of the exercise of quoted options.

10. Reserves

	31 December 2018	30 June 2018
	\$	\$
Share-based payments reserve ¹	2,615,522	2,452,838
Unrealised gains reserve ²	530,924	477,391
Options reserve ³	-	1,989,067
Total reserves	3,146,446	4,919,296
1. Movements in share-based payments reserve:		
Opening balance	2,452,838	2,064,831
Share-based payments expense	162,684	388,007
Closing balance	2,615,522	2,452,838
2. Movements in unrealised gains reserve:		
Opening balance	477,391	832,326
Unrealised (losses)/gains on available for sale assets	53,533	(354,935)
Closing balance	530,924	477,391
3. Movements in option reserve:		
Opening balance	1,989,067	1,989,067
Transfer to contributed equity: exercise of quoted options expired on 25 November 2018	(1,989,067)	-
Closing balance	-	1,989,067

11. 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 2018	30 June 2018
	\$	\$
Within one year	17,070,843	24,340,889
After one year but not more than five years	113,412	1,982,603
After more than five years	184,295	182,260
	17,368,550	26,505,752

12. Events subsequent to reporting date

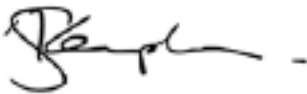
No matters or circumstances have arisen since the end of the reporting period, not otherwise disclosed in this report, which significantly affected, or may significantly affect, the operations of the Group, the results of those operations, or the state of affairs of the Group in future financial years.

Directors' declaration

In accordance with a resolution of the directors of Opthea Limited, we state that:

1. In the opinion of the directors:
 - a. The financial report and the notes thereto are in accordance with the *Corporations Act 2001*, including:
 - i. Giving a true and fair view of the Group's financial position as at 31 December 2018 and of its performance for the half-year ended on that date; and
 - ii. Complying with Australian Accounting Standards and Corporations Regulations 2001 as disclosed in note 2(a) of the financial statements; 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.
2. This declaration has been made after receiving the declarations required to be made to the directors in accordance with section 303(5) of the Corporations Act 2001 for the half-year ended 31 December 2018.

On behalf of the Board:



Geoffrey Kempler
Chairman
Melbourne
25 February 2019

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 2018, 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 consolidated entity's financial position as at 31 December 2018 and its performance for the half-year ended on that date; and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*. As the auditor of 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.

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 2018 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

A handwritten signature in black ink, appearing to read 'S. Vorweg', written over the printed name.

Samuel Vorweg
Partner

Chartered Accountants
Melbourne, 25 February 2019