

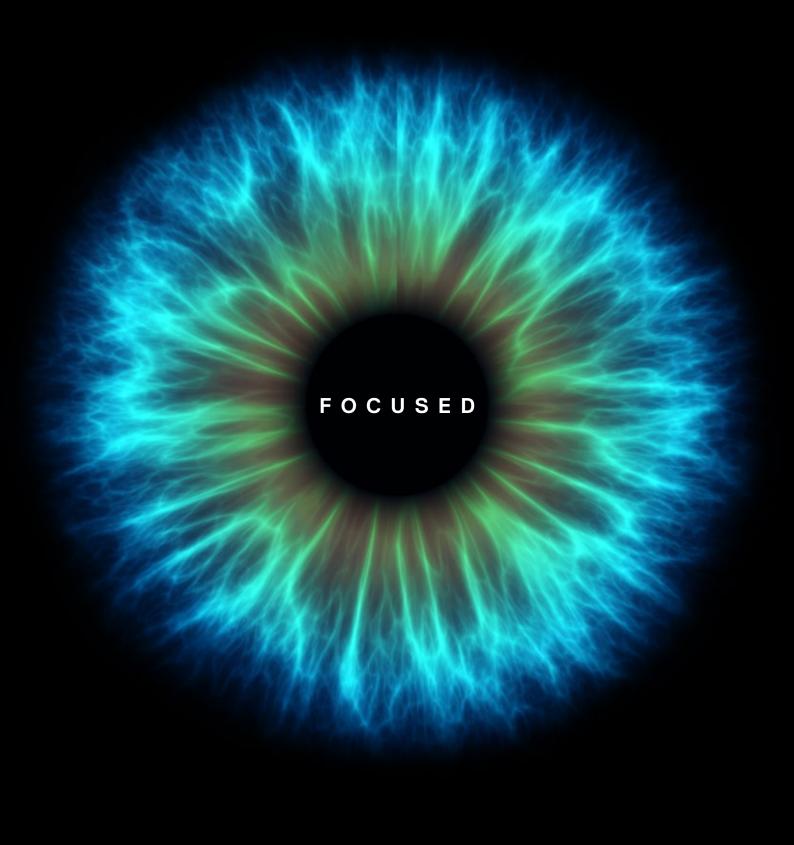
## APPENDIX 4E PRELIMINARY FINAL REPORT

OPTHEA LIMITED ABN 32 006 340 567

## YEAR ENDED 30 JUNE 2018 RESULTS FOR ANNOUNCEMENT TO MARKET

	30 June 2018 \$	30 June 2017 \$	Movement %
Results			
Revenues from ordinary activities	1,143,822	573,421	up 99.5%
Loss from ordinary activities after tax attributable to members	(16,902,240)	(6,192,896)	Loss has increased 172.9%
Loss for the year attributable to members	(16,902,240)	(6,192,896)	Loss has increased 172.9%
NTA Backing			
Net tangible asset backing per ordinary security	0.19	0.27	
Dividend distribution			
No dividends have been paid or declared by the entity since the beginning of	the current reporting perio	d.	

This report is based on the attached audited consolidated financial report.







# OPTHEA IS CLEARLY FOCUSED ON DEVELOPING AND COMMERCIALISING THERAPIES PRIMARILY FOR EYE DISEASES

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#### FOCUSED

## WITH 2020 VISION

### BY 2020, WE ARE ON TRACK TO DELIVER:

- Progress and milestones from our clinical development program investigating OPT-302 in two leading causes of vision loss in the elderly (wet AMD) and diabetic population (DME)
- Completed enrolment and dosing in 351 wet AMD patients in the Phase 2b clinical trial
- Confirmed reporting date of primary data analysis for the Phase 2b wet AMD trial, anticipated early 2020
- Completed patient enrolment and dosing in the Phase 1b/2a DME clinical trial
- An international profile and awareness of Opthea's technology and market opportunity

## wetAMD and DME trials

UPDATE

#### WHAT IS wet AMD

- / The leading cause of blindness in people >55 years
- / Loss of vision in central visual field
- Abnormal vascular growth and leakage of fluid and protein from vessels at the back of the eye leads to swelling and damage to the retina
- / Untreated, leads to chronic and rapid decline in visual acuity

#### wet AMD

#### Initiated 351 patient Phase 2b wet AMD trial

Phase 1/2a Data Analysis \$45m Cap. Raise April'17 Phase 2b wAMD First Patient Dosed (USA) 4Q'17 Ph 2b wAMD First patient Dosed Israel and Europe (Mar'18) Publication Ph1/2a trial results in peer reviewed journal 2H'18

2 0 1 7

2018

1H'17 ' 2H'17

1H'18

2H'18

Initiated Ph1b/2a DME trial (Jan'18) Ph 1b DME Meets Primary Safety Objective 3Q'18 (July'18)

Ph2a DME Open for Enrollment (July'18)

Ph2a DME First patient dosed (July'18)

D M E



#### WHAT IS DME?

- / Leading complication and cause of blindness in diabetics
- / Elevated glucose levels in diabetics damage blood vessels in the retina
- / Members of VEGF family upregulated causing vascular leakage
- Inflammation & fluid accumulation leads to macular swelling and vision loss

Opthea dosed the first patient in the Phase 2b clinical trial in wet AMD patients in December 2017. This randomised, controlled clinical trial is designed to investigate whether addition of OPT-302 to Lucentis® (ranibizumab) therapy improves clinical outcomes, including vision, in patients.

The Phase 2b trial is a multi-centre study currently recruiting patients in the US, Israel and Europe, including the United Kingdom, France, Poland, Hungary, Spain, Latvia, Italy and Czech Republic.

All patients enrolled in the study are 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 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 (6 months or week 24) compared to baseline, in the OPT-302 + Lucentis® groups compared to the Lucentis®-only treated group. 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.

The trial reached the mid-way point of patient recruitment in July 2018 having recruited 176 of the 351 patients that are planned to participate in the study. With patient enrolment progressing well at 113 trial sites globally, Opthea plans to complete patient enrolment in 1Q'19 and report data from the trial in early 2020 following data analysis and completion of the 6 monthly dosing regimen in all patients.



Topline Data: Phase 2a DME

Opthea is investigating OPT-302 administered in combination with Eylea® (aflibercept) on a monthly basis for three months by ocular injection in patients with persistent central-involved DME despite prior sub-optimal responses to standard of care anti-VEGF-A therapy.

The study is a two part multi-centre Phase 1b/2a clinical trial consisting of a sequential dose escalation (Phase 1b) followed by a randomised, controlled dose expansion (Phase 2a).

The Phase 1b enrolled a total of 9 patients into three treatment cohorts of sequential, escalating dose levels of OPT-302 (0.3, 1 and 2 mg) each used in combination

with Eylea® (2mg). The Phase 1b met the primary objective of demonstrating acceptable safety and tolerability.

Following the successful completion of the Phase 1b safety review, the Phase 2a trial opened for patient recruitment. Opthea plans to enrol ~108 DME patients with treatment allocated in a 2:1 ratio to either OPT-302 (2 mg) with Eylea® (2 mg), or Eylea® monotherapy.

The primary objectives of the Phase 2a DME trial are to evaluate the safety /tolerability and efficacy of OPT-302 by determination of the clinical response rate. The clinical response rate is defined as the proportion of patients receiving

combination OPT-302 and Eylea® achieving a ≥5 letter gain in visual acuity at week 12 compared to baseline. In addition, a number of secondary measures will be investigated, including changes in mean visual acuity, diabetic retinopathy severity score, and anatomical parameters such as central subfield thickness (CST) and macular volume from baseline to week 12.

Results from the Phase 2a DME trial are expected in 2019.

## CHAIRMAN AND CEO OVERVIEW

## DEAR FELLOW SHAREHOLDERS

It has been a strong year for the company operationally. We moved forward with our clinical strategy to investigate our lead drug candidate OPT-302 in two retinal eye diseases, wet agerelated macular degeneration (wet AMD) and diabetic macular edema (DME). With two clinical trials currently ongoing, a Phase 2b study of 351 patients with wet AMD and a 117 patient Phase 1b/2a clinical trial in DME, the company remains focussed on advancing OPT-302 through clinical development and addressing the unmet medical need that remains for patients with these diseases.

In this year's report, we have compiled a list of frequently asked questions regarding our technology and programs.

- Q. The blockbuster drugs Lucentis® and Eylea® are approved for the treatment of wet AMD and DME. How is OPT-302 different?
- A. Vessel growth and vascular leakage is primarily driven by members of the Vascular Endothelial Growth Factor (VEGF) family that bind to receptors that are present on vessel walls. Opthea's lead drug development candidate OPT-302, blocks the activity of two members of this family, namely VEGF-C and VEGF-D. Approved therapies for wet AMD and DME include Lucentis® (ranibizumab) and Eylea® (aflibercept). These agents block the activity of VEGF-A, but not VEGF-C or VEGF-D.
- Q. Why is Opthea developing OPT-302 for use in combination with existing standard of care therapies for wet AMD and DME?
- A. Despite regular administration of VEGF-A inhibitors for the treatment of wet AMD and DME, many patients experience sub-optimal gains in visual acuity and/or persistent retinal fluid at the back of the eye. In addition, administration of VEGF-A inhibitors has been associated with compensatory elevations in VEGF-C and VEGF-D, which may continue to drive disease processes and contribute to sub-optimal responses to existing therapies. Combination therapy with OPT-302 and a VEGF-A inhibitor has the potential to improve patient outcomes by more completely blocking the VEGF pathway and addressing mechanisms of resistance to existing therapies.

- Q. What is the potential market opportunity for OPT-302?
- A. Wet AMD and DME prevalence is increasing due to growing aging and diabetic populations. Sales of Lucentis® (Roche/Novartis) and Eylea® (Regeneron/Bayer) exceeded \$9.3BN in 2017. As OPT-302 is being developed to 'add-on' to these existing treatments, rather than 'replace' standard of care, the potential market opportunity for OPT-302 is in excess of \$10BN worldwide, with further growth opportunity if additional ocular indications are pursued.
- Q. Why are you enthusiastic about Opthea's approach?
- A. OPT-302 is novel and differentiated from existing approved agents that block VEGF-A. We have also generated encouraging data from our first-in-human Phase 1/2a clinical trial with OPT-302 in wet AMD patients. This study not only indicated that OPT-302 was well tolerated when administered into the eve. but also suggested that OPT-302 may have additive benefit in improving visual acuity and reducing retinal fluid in wet AMD patients. This is very promising indeed, particularly in a landscape where there is a scarcity of competition with very few novel approaches in development that may offer patients additional clinical benefit to therapies that are currently available.



A. The pharmaceutical industry recognises the very large multi-billion dollar commercial opportunity for novel therapies that may offer additional clinical benefit to patients with retinal eye disease.

With one of the most advanced and

With one of the most advanced and only novel combination approaches in development for the treatment of patients with wet AMD and DME, the pharmaceutical industry is enthusiastic and excited about the potential for OPT-302 to be used in combination with blockbuster therapies such as Lucentis® and Eylea®.

Many pharmaceutical companies are exploring the potential to extend the durability of existing anti-VEGF-A therapies to reduce the number of required injections for patients. Opthea's approach is attractive to the pharmaceutical industry given OPT-302 has the potential to not only extend the dosing interval for patients, but importantly, improve clinical outcomes as well.

Q. When do you anticipate reporting outcomes from the DME and wet AMD trials?

A. In July 2018, Opthea reported that the Phase 1b trial in DME patients successfully met its primary objective of demonstrating acceptable safety and tolerability. Reporting of primary data analysis from the Phase 2a DME and Phase 2b wet AMD trials, which will include visual acuity and secondary outcome measures, is anticipated 2019 and early in 2020 respectively.

Further updates on the anticipated reporting dates will be provided as the trials progress.

Finally, thank-you to our shareholders for your continued support, and to our fellow director Michael Sistenich and management team for another successful year.

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Geoffrey Kempler Chairman Opthea Limited

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Megan Baldwin, PhD CEO & Managing Director Opthea Limited

## DIRECTORS' REPORT

The board of directors of Opthea Limited submits its report for the year ended 30 June 2018 for Opthea and its subsidiaries

#### INFORMATION ABOUT THE DIRECTORS

The names of Opthea Limited's (the Company or Opthea) directors in office during the financial year and until the date of this report are as follows:

#### Geoffrey Kempler

Non-executive director and chairman

#### Megan Baldwin

Managing Director and Chief Executive Officer

#### Michael Sistenich

Non-executive director

The qualifications, experience and special responsibilities of the Company's Directors are as follows.

## Company Secretary MIKE TONROE

BSc(Hons) ACA MAICD

Mike Tonroe, a Chartered Accountant and member of the Australian Institute of Company Directors, was appointed as Chief Financial Officer and Company Secretary on 19 May 2014.

Mike previously held CFO and senior executive and general management positions in a number of international and Australian companies.

Mike is also the Company Secretary for all Opthea subsidiary companies.

#### **GEOFFREY KEMPLER**

B.Sc. Grad. Dipp. App. Soc. Psych

Geoffrey Kempler was appointed as Opthea's chairman in November 2015 and is currently CEO and executive Chairman of Prana Biotechnology. Geoffrey brings extensive experience in investment, business development and the biotechnology industry. As a founder of Prana Biotechnology, he has held both operational roles and been at the forefront of devising and implementing Prana's strategic and commercialization plans. Geoffrey brings experience as Chairman of a dual-ASX-NASDAQ listed biotechnology company, and operational and strategic planning expertise to Opthea.



#### **MEGAN BALDWIN**

PhD. MAICD

Dr Megan Baldwin was appointed CEO and Managing Director in February 2014. Dr Baldwin brings over 20 years of experience focussing on angiogenesis and therapeutic strategies for cancer and ophthalmic indications. Dr Baldwin joined Opthea in 2008 and since then has held various positions, including Head of Preclinical R&D and Chief Executive Officer of Opthea Pty Ltd, the 100% owned subsidiary of Opthea, developing OPT-302 for the treatment of wet age-related macular degeneration. Prior to joining Opthea, she was employed at Genentech (now Roche), the world leader in the field of angiogenesis-based therapies for cancer and other diseases.

Her experience included several years as a researcher in the group of leading angiogenesis expert Napoleone Ferrara, before moving to Genentech's commercial division and having responsibility for corporate competitive intelligence activities. In these roles, she developed extensive commercial and scientific knowledge in the field of anti-angiogenic and oncology drug development. She holds a PhD in Medicine from the University of Melbourne, having conducted her doctoral studies at the Ludwig Institute for Cancer Research on the biology of VEGF-C and VEGF-D, is a member of the Australian Institute of Company Directors and a director of Ausbiotech.

#### MICHAEL SISTENICH

MSc.

Michael Sistenich was appointed non-executive director of Opthea in November 2015 and is Chairman of the remuneration and audit committees.

Michael Sistenich has advised a wide range of global institutions, high net worth individuals and companies on healthcare investments over the past 20 years. He is a healthcare specialist in international investment management and investment banking, and led the Bell Potter team which advised the Company through the \$17.4M capital raising in November 2014. Michael Sistenich is currently a director of Nohla Therapeutics, and previously served as Director of International Equities and Head of Global Healthcare Investments at DWS Investments, Deutsche Bank Frankfurt. Michael has long standing capital market connections and experience in the global healthcare investment community.



### DIRECTORS' REPORT (CONT.)

## DIRECTORSHIPS OF OTHER LISTED COMPANIES

Directorships of other listed companies held by directors in the three years immediately before the end of the financial year are as follows:

Director	Company	Period of directorship
Geoffrey Kempler	Prana Biotechnology Limited	Since 2000

#### **DIRECTORS' INTERESTS**

At the date of this report, the relevant interests of each director of the Company in the contributed equity of the Company are as follows:

	Fully paid ordinary shares	Quoted options	Options granted under LTIP and NED Plans
Megan Baldwin <sup>1</sup>	1,643,223	11,500	4,000,000
Geoffrey Kempler	615,246	285,714	2,000,000
Michael Sistenich	520,178	-	1,000,000

<sup>1</sup> Holding of ordinary shares includes 1,500,000 ordinary shares issued on 1 July 2015 subject to a holding lock that expired on 1 July 2016.

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#### SHARE OPTIONS

As at 30 June 2018 and the date of this report, details of Opthea's unissued ordinary shares and interests under option are as follows:

#### **Unissued ordinary shares**

At 30 June 2018 the company had on issue 47,073,324 quoted options to purchase ordinary shares with an exercise price of \$0.27 and expiry date of 25 November 2018. During the year, 1,063,518 options (2017: 1,570,255) were exercised, 160,000 quoted options have been exercised since the end of the financial year.

No quoted options expired during or since the end of the financial year.

#### Long Term Incentive and Non-Executive Director Share and Option Plans

During the 2016 and 2018 financial years the Company granted 10,125,000 options to purchase ordinary shares to directors and employees under the Long Term Incentive (LTIP) and Non-Executive Director Share and Option (NED) Plans. The 1,000,000 options granted to Bell Potter Securities Limited were exercised during the financial year.

Grant date	Expiry date	Granted to	Exercise price	of options granted
7 March 2016	7 March 2021	Directors under the LTIP and NED plan	\$0.48	7,000,000
31 March 2016	1 January 2022	Employees under the LTIP	\$0.48	2,575,000
23 August 2017	1 January 2023	Employees under the LTIP	\$1.16	500,000
				10,075,000

The Remuneration Report section of this report contains details on the terms and conditions of the options granted under the Company's LTIP and NED Plans.

#### DIVIDENDS

No cash dividends have been paid, declared or recommended during or since the end of the financial year by the Company.

#### PRINCIPAL ACTIVITIES

The principal activity of Opthea Limited is to develop and commercialise therapies primarily for eye disease. Opthea's lead asset, OPT-302, is a soluble form of VEGFR-3 in clinical development as a novel therapy for wet age-related macular degeneration (wet AMD) and diabetic macular edema (DME). Wet AMD and DME are leading causes of blindness in the elderly and diabetic populations respectively, and are increasing in prevalence worldwide.

Opthea's principal activities in 2017-18 included initiation and patient recruitment into two clinical trials, a Phase 1b clinical trial in DME patients and a Phase 2b study in treatment-naïve wet AMD patients. In addition, Opthea conducted a number of activities to support both clinical development programs, including interactions with regulatory agencies and manufacturing of OPT-302 for use in clinical studies.

Opthea's development activities are based on an extensive intellectual property portfolio covering key targets (Vascular Endothelial Growth Factors VEGF-C, VEGF-D and VEGF Receptor-3) for the treatment of diseases associated with blood and lymphatic vessel growth (angiogenesis and lymphangiogenesis respectively), as well as vascular leakage. Angiogenesis and vascular leakage are key hallmarks of several eye diseases, including wet AMD and DME.

#### **OPERATING AND FINANCIAL REVIEW**

#### **Financial performance**

The consolidated results of Opthea and its subsidiaries (the Group) for the year reflect the Group's investment in advancing its OPT-302 ophthalmology program.

A summary of the results is as follows:

- The major expenditure of the Group has been in relation to R&D, in particular costs associated with the Phase 2b and Phase1b/2a clinical trials of OPT-302 for wet AMD and DME, and manufacture of clinical grade OPT-302 drug product;
- Direct R&D expenditure (excluding personnel costs) amounted to \$24,891,534 (2017: \$4,838,300). Including personnel costs and other R&D support costs which are recognised through the administrative cost centre, total expenditure in R&D amounted to \$27,111,137 (2017: \$6,229,346);
- Opthea received an R&D tax incentive payment during the year of \$2,709,765 (2017: \$2,643,553);

The consolidated net loss of the Group for the year was \$16,902,240 after an income tax benefit of \$12,017,248 (2017: loss of \$6,192,896 after an income tax benefit of \$3,167,912).

#### FINANCIAL POSITION

The Group statement of financial position includes the following key balances:

- Consolidated cash balances as at 30 June 2018 amounted to \$32,510,230 (2017: \$51,959,906);
- Receivables of \$12,410,980 (2017: \$3,218,731) include the Opthea Group's expected refund of R&D tax incentives for the year to June 2018 of \$12,017,248 (2017: \$2,709,765);
- The Group has a net current asset surplus of \$37,349,456 (2017: \$53,329,849);
- The net tangible asset backing per share as at 30 June 2018 was \$0.19 (2017: \$0.27); Opthea's share price was \$0.53 (2017: \$0.75).

#### **Opthea's Technology**

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'. Vessel growth and vascular leakage are primarily driven by members of the vascular endothelial growth (VEGF) factor family, and elevated levels of these signals are associated with disease progression.

Current treatments for wet AMD and DME include the multi-billion dollar therapies Lucentis® (ranibizumab), Eylea® (aflibercept) and Avastin® (bevacizumab), which share a common mechanism of action by inhibiting a member of the VEGF family, known as VEGF-A.

Despite the widespread use of VEGF-A inhibitors for the treatment of retinal diseases, and their commercial success which is in excess of USD9 billion per annum in global revenue for Lucentis® and Eylea® alone, there remains a major unmet medical need as many patients experience sub-optimal gains in visual acuity and/or persistent retinal fluid despite regular administration of existing treatments.

Opthea's OPT-302 blocks two novel members of the VEGF family that stimulate blood vessel growth and vascular leakage, namely VEGF-C and VEGF-D. By combining administration of OPT-302 with a VEGF-A inhibitor, a more complete blockade of the VEGF pathway can be achieved. 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 for wet AMD and DME.

### DIRECTORS' REPORT (CONT.)

Opthea's objective is therefore to develop OPT-302 as a complementary medicine to be used in conjunction with existing VEGF-A inhibitors such as Lucentis® and Eylea®.

Opthea's approach for the treatment of retinal diseases with OPT-302 is novel and differentiated from existing approved agents that block VEGF-A. By developing OPT-302 as a combination agent, there is great potential to improve upon the current therapeutic options for both wet AMD and DME patients and prevent chronic decline in vision that occurs in many patients despite receiving ongoing anti-VEGF-A therapy.

#### Operational update

Following the reporting of successful outcomes from Opthea's Phase 1/2a clinical trial of OPT-302 in 51 wet AMD patients in April 2017, the company has expanded and diversified its clinical development program. Opthea is currently investigating OPT-302 in two clinical trials to determine if OPT-302 improves visual acuity in patients receiving standard of care therapy for wet AMD and DME:

- A randomised, controlled Phase 2b clinical trial of OPT-302 in treatment naïve wet AMD patients, and
- / A Phase 1b/2a clinical trial investigating OPT-302 in patients with persistent, central involved diabetic macular edema (DME).

The successful and oversubscribed \$45m fundraising in April 2017 funds Opthea through the Phase 2b wet AMD and Phase 1b/2a DME clinical studies described above. To facilitate initiation and progression of the company's expanded clinical development program, Opthea has interacted with regulatory agencies in the US, Europe and Israel and entered into research and development contracts with various third parties, including a global contract research organisation, to provide services for the conduct of the clinical trials.

These activities and forecast expenditure as outlined in note 25 (page 52) were anticipated and are consistent with use-of-funds disclosures to shareholders in support of the April 2017 fundraising.

#### Phase 2b wAMD clinical trial

This randomised, controlled clinical trial is designed to investigate whether addition of OPT-302 to Lucentis® therapy over a 6 month period improves clinical outcomes, including visual acuity, in wet AMD patients.

All patients enrolled in the study are newly diagnosed, treatmentnaïve 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 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 (6 months or week 24) compared to baseline, in the OPT-302 + Lucentis® groups compared to the Lucentis®-only treated group. 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.

Opthea dosed the first patient in the Phase 2b clinical trial in wet AMD patients in December 2017, and in March 2018, the first patients enrolled into the study from Europe and Israel were dosed.

With 113 sites now actively recruiting patients from 10 countries, including the US, Israel, United Kingdom, France, Poland, Hungary, Spain, Latvia, Italy and Czech Republic, we were pleased to report that the trial reached the mid-way point of patient enrolment in July 2018. With over 200 patients out of the total 351 patients currently enrolled into the trial, we anticipate completion of patient enrolment in 1Q'19 and reporting of data from the study early in 2020 following data analysis and completion of the 6 monthly dosing regimen in all patients.

#### 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.

In December 2017, the first US based clinical trial sites for this study were activated and the first patient dosed in the Phase 1b trial was in the US in February 2018.

This multi-centre clinical trial, which will also enrol patients in Australia, is a two-part design consisting of a Phase 1b dose escalation of OPT-302 (0.3, 1 and 2 mg) used in combination with the VEGF-A inhibitor Eylea® (aflibercept, 2 mg), followed by a Phase 2a randomised, controlled dose expansion with treatment allocated in a 2:1 ratio to either OPT-302 with Eylea®, or Eylea® monotherapy. Opthea plans to enrol ~117 patients with persistent central involved diabetic macular edema despite prior anti-VEGF-A therapy with each patient dosed on a monthly basis for 3 months via intravitreal injection.

The primary objectives of the study are to evaluate the safety/tolerability and efficacy of OPT-302 by determination of the clinical response rate as defined by the proportion of patients receiving combination OPT-302 and Eylea® achieving a  $\geq 5$  letter gain in visual acuity (VA) compared to baseline at week 12.

In addition, a number of secondary measures will be investigated, including changes in mean visual acuity, diabetic retinopathy severity score, and anatomical parameters such as central subfield thickness (CST) and macular volume from baseline to week 12.

In July 2018, Opthea announced that the Phase 1b dose escalation trial had successfully met the primary objective of demonstrating acceptable safety and tolerability in persistent central-involved DME patients. This was an important milestone as it was the first time OPT-302 had been administered in patients with DME and in combination with Eylea®. The encouraging safety profile demonstrated in the Phase 1b study builds on Opthea's growing clinical experience from the completed Phase 1/2a and ongoing Phase 2b clinical trials in wet AMD patients who have received OPT-302 in combination with the VEGF-A inhibitor Lucentis®.

Results from the Phase 2a DME trial are expected in 2019.

#### Intellectual property

Opthea owns a patent family covering the OPT-302 molecule and uses thereof, extending out to February 2034. Patents have already been granted in the United States, Australia, South Africa, Singapore and Colombia and applications are pending in a further 14 countries. Grant of the US patent in August 2017 was a key milestone for Opthea, with the granted patent including 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.

With a share register comprised largely of global institutional healthcare funds, Opthea continued to raise the profile of the company's technology to the international and local investment community, as well as internationally recognised key opinion leaders and clinical ophthalmology community. In January Opthea attended the 36th Annual J.P. Morgan Conference in San Francisco. 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.

## SIGNIFICANT CHANGES IN THE STATE OF AFFAIRS

In the opinion of the directors, there were no significant changes in the state of affairs of the Company that occurred during the financial year under review.

#### **FUTURE DEVELOPMENTS**

Opthea continues to focus on the significant opportunity residing in the OPT-302 program. Operationally, the company is advancing the clinical development of OPT-302 to key commercial milestones, most notably the primary data analysis of the Phase 1b/2a clinical trial in DME anticipated in calendar year 2019, and reporting of outcomes from the larger Phase 2b clinical trial in treatment-naïve wet AMD patients anticipated in 2020.

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

- Complete patient enrolment in the US, Europe and Israel for the Phase 2b clinical trial in treatment naïve wet AMD patients;
- Complete the 6-monthly dosing regimen in all patients enrolled in the Phase 2b wet AMD trial;
- / Complete patient recruitment and dosing of patients enrolled into the Phase 2a clinical trial in DME;
- Publish the outcomes of the Phase 1/2a study of OPT-302 in wet AMD patients in a peer reviewed journal;
- Continue to liaise with and obtain advice from key opinion leaders in ophthalmology to ensure our clinical program is optimally designed and executed;
- Raise Opthea's profile and an understanding of the company's technology to the international investment and clinical ophthalmology community.

## SIGNIFICANT EVENTS AFTER BALANCE DATE

There were no significant events after 30 June 2018 to report.

#### **ENVIRONMENTAL REGULATIONS**

The Company is not subject to significant environmental regulations.

#### INDEMNIFICATION AND INSURANCE

During the financial year ended 30 June 2018, the Company indemnified its directors, the company secretary and executive officers in respect of any acts or omissions giving rise to a liability to another person (other than the Company or a related party) unless the liability arose out of conduct involving a lack of good faith. In addition, the Company indemnified the directors, the company secretary and executive officers against any liability incurred by them in their capacity as directors, company secretary or executive officers in successfully defending civil or criminal proceedings in relation to the Company. No monetary restriction was placed on this indemnity.

The Company has insured its directors, the company secretary and executive officers for the financial year ended 30 June 2018. Under the Company's Directors' and Officers' Liabilities Insurance Policy, the Company shall not release to any third party or otherwise publish details of the nature of the liabilities insured by the policy or the amount of the premium. Accordingly, the Company relies on section 300(9) of the *Corporations Act 2001* to exempt it from the requirement to disclose the nature of the liability insured against and the premium amount of the relevant policy.

### DIRECTORS' REPORT (CONT.)

#### **DIRECTORS' MEETINGS**

The number of meetings of directors and meetings of committees of the board held during the year are set out below. Attendance by the directors at these meetings as relevant to each of them is as shown. It is the Company's practice to invite all directors to committee meetings irrespective of whether they are members.

		Meetings of	committees
Directors' meetings		Audit & Risk	Remuneration
Number of meetings held:	8	3	2
Number of meetings attended:			
Geoffrey Kempler	7	3	2
Michael Sistenich	8	3	2
Megan Baldwin	8	3	2

#### Committee membership

During the year, the Company had Audit and Risk, Remuneration and Nomination committees.

Members acting on the committees of the board during the year were:

Audit & Risk	Nomination	Remuneration	
Michael Sistenich (Chairman)	Michael Sistenich (Chairman)	Michael Sistenich (Chairman)	
Geoffrey Kempler	Geoffrey Kempler	Geoffrey Kempler	

## AUDITOR'S INDEPENDENCE DECLARATION

The directors have obtained a declaration of independence from Deloitte Touche Tohmatsu, the Company's auditors, which is set out on page 20 and forms part of the directors' report for the financial year ended 30 June 2018.

## PROCEEDINGS ON BEHALF OF THE COMPANY

There were no persons applying for leave under section 237 of the *Corporations Act 2001* to bring, or intervene in, proceedings on behalf of the Company.

#### **CORPORATE GOVERNANCE**

The board aims to achieve and show the highest standards of corporate governance. The Company has adopted the third edition of the Corporate Governance Principles and Recommendations. These were released by the ASX Corporate Governance Council on 27 March 2014. They became effective for financial years beginning on or after 1 July 2014.

The board approved the 2018 Corporate Governance Statement on 28 August 2018. The Corporate Governance Statement is available on Opthea Limited's web site at http://www.opthea.com/pub/pdf/Opthea\_CorporateGovernanceStatement2018.pdf

#### **REMUNERATION REPORT - AUDITED**

#### **Principles of compensation**

Compensation packages include a mix of fixed and variable compensation and long-term performance based incentives.

#### **Fixed compensation**

The level of fixed remuneration is set to provide a base level of compensation which is both appropriate to the position and is competitive in the market.

The remuneration committee accesses external advice independent of management if required.

Fixed compensation comprises salary and superannuation and is reviewed every 12 months by the remuneration committee.

#### Performance linked compensation

Short Term Incentives (STI): The objective of STI is to link the achievement of the Company's operational targets with the remuneration received by the executives charged with meeting those targets. The total potential STI available is set at a level that provides sufficient incentive to the executive to achieve the operational targets at a cost to the Company that is reasonable in the circumstances.

Actual STI payments in the form of cash bonuses to key management personnel (KMP) depend on the extent to which specific targets set at the beginning of the financial year (or shortly thereafter) are met. The targets consist of a number of Key Performance Indicators (KPIs) covering corporate objectives and individual measures of performance. Individual KPIs are linked to the Company's development plans.

On an annual basis, after consideration of performance against KPls, the remuneration committee determines the amount, if any, of the STI to be paid to KMP. Payments of the STI bonus are made in the following reporting period.

The remuneration committee considered the STI payment for the 2018 financial year in July 2018. Based on the achievement of operational objectives in the financial year, the remuneration committee has determined there will be \$240,775 STI bonus paid to KMP for the 2018 financial year (2017: \$383,750).

Long term incentive plan (LTIP): The objective of the LTIP is to reward KMP in a manner that aligns this element of compensation with the creation of shareholder wealth. LTIP grants are made to KMP and employees who are able to influence the generation of shareholder wealth and have a direct impact on the Company's performance and development. Option vesting conditions are based on continued service to the Company by the KMP.

The Company implemented an LTIP to attract, retain and motivate eligible employees, essential to the continued growth and development of the Company. The LTIP was approved by shareholders at the Company's 2014 AGM. The limit of the Company's share capital to be granted under the LTIP was increased to 10% at the 2016 EGM.

## DIRECTORS' REPORT (CONT.)

#### Consequences of performance on shareholder wealth

In considering the Company's performance and benefits for shareholder wealth, the remuneration committee have regard to the following indices in respect of the current and previous four financial years.

	2018 \$	2017 \$	2016 \$	2015 \$	2014 \$
Revenue	1,143,822	573,421	765,274	939,008	878,083
Loss before tax	(28,919,488)	(9,360,808)	(8,100,978)	(8,121,254)	(6,849,021)
Tax benefit	12,017,248	3,167,912	1,569,204	2,720,260	2,859,403
Loss after tax	(16,902,240)	(6,192,896)	(6,531,774)	(5,400,994)	(3,989,618)
	2018 \$	2017 \$	2016 \$	2015 \$	2014 \$
Basic loss per share	(0.08)	(0.04)	(0.04)	(0.05)	(0.08)
NTA backing per share @ 30 June	0.19	0.27	0.10	0.15	0.22
Opthea share price @ 30 June	0.53	0.75	0.50	0.19	0.19

Change in share price is one of the financial performance targets considered in setting STI.

#### **Service contracts**

Dr Megan Baldwin, CEO and Managing Director, is employed under an ongoing contract that commenced on 24 February 2014. Under the terms of the present contract (including any subsequent board approvals relating to fixed remuneration) Megan:

- / Receives fixed remuneration of \$360,500 per annum from 1 July 2017.
- May resign from her position and thus terminate this contract by giving three months' notice.

On resignation, any unvested LTI options or conditional rights will be forfeited. The Company may terminate this employment agreement by providing:

- / 3 months' notice; or
- / Payment in lieu of the notice period (as detailed above) based on the fixed component of Megan's remuneration.

On termination notice by the Company, any LTIP options that have vested or that will vest during the notice period will be released. Options granted that have not yet vested will be forfeited.

The Company may terminate the contract at any time without notice if serious misconduct has occurred.

Where termination with cause occurs, Megan is only entitled to that portion of remuneration that is fixed, and only up to the date of termination. On termination with cause, any unvested options will immediately be forfeited.

The CFO and Company Secretary has an ongoing contract. The Company may terminate the employment agreement by providing three months' notice or providing payment in lieu of the notice period (based on the fixed component of remuneration).

The Company may terminate Mike Tonroe's contract at any time without notice if serious misconduct has occurred. Where termination with cause occurs the executive is only entitled to that portion of remuneration that is fixed and only up to the date of termination.

#### Non-executive directors

The base non-executive director fee for Chairman is \$90,405 per annum and \$60,000 per annum for other non-executive directors. Base fees cover all main board activities and membership of all board committees.

Non-executive directors are not provided with retirement benefits apart from statutory superannuation.

The Company implemented a non-executive director share and option plan (NED Plan) following its approval at the 2014 AGM. Under the NED Plan, present and future non-executive directors may:

- / elect to receive newly issued ordinary shares (Shares) or options to acquire newly issued Shares in lieu of receiving some or all of their entitlement to their director's existing cash remuneration (in accordance with article 61.8 of the Company's constitution);
- / be awarded newly issued Shares or options to acquire newly issued Shares in lieu of additional cash remuneration in respect of services provided to the Company which in the opinion of the Board are outside the scope of the ordinary duties of

- the relevant director (in accordance with article 61.5 of the Company's constitution); and/or
- otherwise be awarded newly issued Shares or options to acquire newly issued Shares as part of the directors' remuneration in addition to any existing cash remuneration paid to directors (if any).

Advantages of the NED Plan are that it:

- assists the Company in preserving its cash for use towards advancing the Company's lead molecule, OPT-302, through Phase 2 clinical studies;
- gives non-executive directors an opportunity to demonstrate their commitment and support for the Company through sacrificing some or all of their director's fees for Shares or options in Opthea; and
- / provides the Company with further flexibility in the design of the directors' remuneration packages and in turn assists the Company with retaining existing directors and attracting new additional directors with the relevant experience and expertise, in both cases to further advance the prospects of the Company.

## DIRECTORS' REPORT (CONT.)

#### Directors' and executive officers remuneration

Details of the nature and amount of each major element of remuneration of each director and key management personnel of the Company are:

			Short Term	Post Employ- ment	Long Term	Termina- tion benefits	Share- based payment		Total
		Salary & Fees \$	Cash bonus¹ \$	Superan- nuation \$	Long Service Leave \$	Termina- tion Pay \$	Options \$	Total \$	perfor- mance related %
Non-Executive d	irectors	s:							
Geoffrey Kempler	2018	90,405	-	8,589	-	-	44,267	143,261	31%
	2017	90,405	_	8,589	_	_	150,558	249,552	60%
Michael Sistenich	2018	60,000	-	5,700	-	-	22,133	87,833	25%
	2017	60,000	_	5,700	_	-	75,279	140,979	53%
Sub-total									
Non-executive	2018	150,405	-	14,289	-	-	66,400	231,094	29%
directors	2017	150,405	_	14,289	_	-	225,837	390,531	58%
Executive director	ors:								
Megan Baldwin	2018	360,500	180,250	50,873	_	_	88,533	680,654	39%
	2017	350,000	325,000	49,875	_	-	301,116	1,025,991	61%
Other Key Manag	gement	Personnel:							
Mike Tonroe	2018	242,100	60,525	28,581	-	-	41,790	373,164	27%
	2017	235,000	58,750	27,906	_	_	101,908	423,564	38%
Totals	2018	753,005	240,775	93,742	-	_	196,723	1,284,913	34%
	2017	735,405	383,750	92,070	-	_	628,861	1,840,086	55%

<sup>1</sup> Bonuses are paid in the financial year following the year in which they are earned.

#### **Equity instruments**

All options refer to options over ordinary shares of Opthea Limited which are exercisable on a one-for-one basis under the Long Term Incentive (LTIP) and Non-executive share and options (NED) plans.

#### Options over equity instruments granted as compensation

Details of options over ordinary shares in the Company that were granted as compensation to KMP during the reporting period and details of options that vested during the reporting period are as follows:

	During the financial year								
Name	Number of options granted	Grant date	Fair value per option at grant date	Exercise price per option \$	Expiry date	Number of options vested			
Megan Baldwin	4,000,000	7 March 2016	0.19	0.48	7 March 2021	4,000,000			
Geoffrey Kempler	2,000,000	7 March 2016	0.19	0.48	7 March 2021	2,000,000			
Michael Sistenich	1,000,000	7 March 2016	0.19	0.48	7 March 2021	1,000,000			
Mike Tonroe	800,000	31 March 2016	0.24	0.48	31 March 2022	528,000			

All options expire on the earlier of their expiry date or termination of the individual's employment. Option vesting is conditional on the individual being employed or in office. The options are exercisable up to three years after they vest.

#### Exercise of options granted as compensation

During the reporting period, no shares were issued on the exercise of options previously granted as compensation.

## DIRECTORS' REPORT (CONT.)

#### Details of options affecting current and future remuneration

Details of vesting profiles of the options held by each KMP of the Company are:

	Number of options	Grant date	% vested	% forfeited <sup>1</sup>	Financial years in which grant vests	Vesting Conditions
Megan Baldwin	1,320,000	7 March 2016	100%	0%	1 July 2015	Continued
	1,320,000	7 March 2016	100%	0%	1 July 2016	service
	1,360,000	7 March 2016	100%	0%	1 July 2017	
Geoffrey Kempler	660,000	7 March 2016	100%	0%	1 July 2015	Continued
	660,000	7 March 2016	100%	0%	1 July 2016	service
	680,000	7 March 2016	100%	0%	1 July 2017	
Michael Sistenich	330,000	7 March 2016	100%	0%	1 July 2015	Continued
	330,000	7 March 2016	100%	0%	1 July 2016	service
	340,000	7 March 2016	100%	0%	1 July 2017	
Mike Tonroe	264,000	31 March 2016	100%	0%	1 July 2016	Continued
	264,000	31 March 2016	100%	0%	1 July 2017	service
	272,000	31 March 2016	0%	0%	1 July 2018	

<sup>1</sup> The percentage forfeited in the year represents the reduction from the maximum number of options available to vest due to vesting criteria not being achieved.

#### Movements in equity instruments

No options over ordinary shares in the Company were granted to or exercised by KMPs during the reporting period.

#### **Options over equity instruments**

The movement during the reporting period by number of rights and options over ordinary shares in Opthea Limited held directly, indirectly or beneficially, by each KMP, including their related parties, is as follows:

Number of options:		Held at 1 July	Granted as compen- sation	Options exercised	Lapsed	Forfeited	Held at 30 June	Vested during the year	Vested and exercis- able
Megan Baldwin	2018	4,000,000	_	_	_	_	4,000,000	1,360,000	4,000,000
	2017	4,000,000	-	-	-	-	4,000,000	1,320,000	2,640,000
Geoffrey Kempler	2018	2,000,000	_	-	_	-	2,000,000	680,000	2,000,000
-	2017	2,000,000	-	-	_	_	2,000,000	660,000	1,320,000
Michael Sistenich	2018	1,000,000	_	-	_	_	1,000,000	340,000	1,000,000
	2017	1,000,000	_	_	_	-	1,000,000	330,000	660,000
Other executives									
Mike Tonroe	2018	800,000	_	_	_	_	800,000	264,000	528,000
	2017	800,000	-	-	_	_	800,000	264,000	264,000
Total	2018	7,800,000	_	_	_	_	7,800,000	2,644,000	7,528,000
	2017	7,800,000	_	_	_	_	7,800,000	2,574,000	4,884,000

#### **KEY MANAGEMENT PERSONNEL TRANSACTIONS**

#### Movements in shares

The movement during the reporting period in the number of ordinary shares in Opthea Limited held, directly, indirectly or beneficially, by each KMP including their related parties is as follows:

Number of Ordinary Shares:		Balance at beginning of period 1 July	Granted as remunera- tion	On Exercise of Options	Purchased in the year	Appointed/ (resigned) during the year	Balance at end of period 30 June
Non-executive directors							
Geoffrey Kempler	2018	615,246	_	_	_	_	615,246
	2017	574,429	_	_	40,817	_	615,246
Michael Sistenich	2018	520,178	_	_	_	_	520,178
	2017	320,000	_	_	200,178	_	520,178
Executives							
Megan Baldwin	2018	1,643,223	_	_	_	_	1,643,223
	2017	1,533,674	_	_	109,549	_	1,643,223
Mike Tonroe	2018	_	_	_	_	_	_
	2017	_	_	_	_	_	_
Total	2018	2,778,647	_	_	_	_	2,778,647
	2017	2,428,103	_	_	350,544	_	2,778,647

This report has been signed in accordance with a resolution of the directors made pursuant to S.298 (2) of the *Corporations Act 2001* on 28 August 2018.

For and on behalf of the board:

Megan Baldwin

CEO & Managing Director Opthea Limited

Melbourne 28 August 2018

## DECLARATION OF INDEPENDENCE

### Deloitte.

The Board of Directors Opthea Limited Suite 0403, Level 4, 650 Chapel Street SOUTH YARRA VIC 3141 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

28 August 2018

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 audit of the financial statements of Opthea Limited for the financial year ended 30 June 2018, I declare that to the best of my knowledge and belief, there have been no contraventions of:

- (i) the auditor independence requirements of the *Corporations Act 2001* in relation to the audit; and
- (ii) any applicable code of professional conduct in relation to the audit.

Yours faithfully

DELOTTE TOUCHE TOHMATSU

DELOITTE TOUCHE TOHMATSU

Samuel Vorwerg

Partner

Chartered Accountants

Liability limited by a scheme approved under Professional Standards Legislation.

Member of Deloitte Touche Tohmatsu Limited

## MANAGEMENT TEAM







#### MEGAN BALDWIN PHD. MAICD

Chief Executive Officer and Managing Director

Dr Megan Baldwin has been appointed CEO and Managing Director effective 24 February 2014.

Dr Baldwin brings over 20 years of experience focusing on angiogenesis and therapeutic strategies for ophthalmic and cancer indications. Since joining positions, including Head of Preclinical R&D and Chief Executive Officer of Opthea Pty Ltd, the 100% owned subsidiary of Opthea, developing OPT-302 for the treatment of wet age-related macular degeneration. Prior to joining Opthea, Dr Baldwin was employed at leader in the field of angiogenesis-based therapies for cancer and other diseases. Her experience included several years as a researcher in the group of leading angiogenesis expert Napoleone Ferrara, before moving to Genentech's commercial division and having responsibility for corporate competitive intelligence extensive commercial and scientific knowledge in the field of anti-angiogenic and oncology drug development. Megan holds a PhD in Medicine from Ludwig Institute for Cancer Research on the biology of VEGF-C and VEGF-D, is a member of the Australian Institute of Company Directors and a director of Ausbiotech.

#### MIKE TONROE BSC(HONS), ACA, MAICD

Chief Financial Officer and Company Secretary

Mike Tonroe is a Chartered Accountant and was appointed Chief Financial Officer and Company Secretary in May 2014 and is accountable directly to the board, through the chair, on all matters to do with the proper functioning of Opthea's board. Prior to joining Opthea, Mike was the Chief Financial Officer and Company Secretary at the Australian Synchrotron in Melbourne.

Mike has over 20 years' experience of financial management in board-level positions for private and listed companies in Australia, UK, the US and Canada. Mike holds a Graduate Degree in Business Studies from Buckingham University and is a member of the Australian Institute of Company Directors. Mike is also the Company Secretary for all of the Company's subsidiaries.

## RICHARD CHADWICK PHD

Head of Intellectual Property

Richard Chadwick, who joined Opthea in February 2008, is qualified as both a European and Australian patent attorney. Richard joined Opthea from FB Rice & Co, where he had been working for five years in the Biotechnology Group. Prior to that, Richard had 10 years' experience in intellectual property in the UK. This included working as an in-house attorney at Dow Corning Limited and five years working as an in-house attorney at Unilever.

### MANAGEMENT TEAM (CONT.)







#### MIKE GEROMETTA PHD Head of CMC Development

Mike Gerometta has been with Opthea since December 2008 and is principally research and cGMP manufacturing activities. Mike has over 20 years' industry, most recently as Chief Operating Officer of Q-Gen, QIMR's translational also spent 19 years at Agen Biomedical, roles, most recently as Research and Product Development Director. In this role he was responsible for the chemistry, manufacturing and controls (CMC), pre-clinical program and patent project, a blood clot imaging agent. Previously, he has worked at Biotech earlier positions at Agen, developed numerous successful immunodiagnostic assays for the medical, veterinary and food industries across various diagnostic platforms for the laboratory and pointof-care. He was awarded his PhD in biotechnology from the Queensland University of Technology and has a degree in chemistry from the University of Technology in Sydney.

#### IAN LEITCH PHD

Director - Clinical Research

lan Leitch has been Director of Clinical Research of Opthea Technologies Ltd since September 2011. He has over 15 years of research and management experience from drug discovery through pharmaceutical companies. For the five years prior to joining Opthea, he was a member of the Medical Sciences group at Amgen Inc in Thousand Oaks, California, involved in the development of novel therapeutics in Amgen's oncology pipeline. In his role as Senior Manager in the Early Development Oncology Therapeutic Area, he had responsibility for the oversight, design, management and execution of Prior to joining Amgen, he spent eight years at Miravant Medical Technologies positions of increasing responsibility, including Senior Program Manager for Cardiovascular Research and Clinical Study Director for Ophthalmology. At Miravant, he managed pre-clinical efficacy studies, developed relationships with Key Opinion Leaders and designed Phase 1–2 clinical studies in a collaboration with the cardiovascular device company Guidant Inc. He previously held the position of NHMRC Senior Research Officer at the University of Newcastle, and was based at the John Hunter Hospital in Australia. He received his PhD from the Department of Pharmacology, Faculty of Medicine, at Monash University in 1993 and completed part of the degree at the University of California, Santa Barbara as part of an Education Abroad Program Scholarship.

#### **CLARE PRICE**

Director - Clinical Research

Clare Price was appointed Director of Clinical Research at Opthea in July 2016, and brings over 20 years of clinical and drug development experience to the company. Clare started her career in the main R&D function of SmithKline Beecham in Harlow, UK.

She spent over 8 years in various clinical roles within the company with responsibility for the design, management and execution of clinical studies from phase 1 to 3 across a number a therapeutic areas.

For the remaining three years Clare formed part of the project management group of the newly merged GlaxoSmithKline, responsible for the project management of full drug development programs from molecule inception through non-clinical and clinical studies, regulatory aspects and commercialisation. She then moved to Melbourne, where she has held senior clinical roles in two ASX-listed biotechnology companies, firstly Acrux, and then Starpharma. Over the nine years that Clare spent at Starpharma she successfully built, implemented and delivered phase 2 and 3 clinical programmes, including extensive regulatory interaction and negotiation, which led to the successful commercialisation of the lead candidate product.

Clare is a registered pharmacist, with a degree in Pharmacy, from the University of Bath in the UK.



## **ANNETTE LEAHY**Director – Clinical Research

Annette Leahy commenced at Opthea in August 2017 as Director of Clinical Research. Annette has 20 years clinical research experience including operational and project management roles across biotechnology, pharmaceutical, and Annette held senior operational roles at Swisse and Novotech successfully building clinical trial teams and departments. Annette also has 12 years project management experience including leading a global influenza clinical trials program under a US government contract at Biota, managing early phase clinical Network and managing European clinical projects while living in the UK and working for Mitsubishi Tanabe Pharma Europe. Annette has a Bachelor of Health Information Management from



## FINANCIAL REPORT CONTENTS **25** CONSOLIDATED STATEMENT 28 CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR YEAR ENDED 30 JUNE 2018 THE YEAR ENDED 30 JUNE 2018 29 NOTES TO THE CONSOLIDATED **26** CONSOLIDATED STATEMENT OF FINANCIAL STATEMENTS FINANCIAL POSITION AT 30 JUNE 2018 **57** DIRECTORS' DECLARATION **27** CONSOLIDATED STATEMENT FOR THE YEAR ENDED 30 JUNE 2018 OF CHANGES IN EQUITY FOR **58** INDEPENDENT AUDITOR'S REPORT THE YEAR ENDED 30 JUNE 2018

**62** ASX ADDITIONAL INFORMATION

# CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE YEAR ENDED 30 JUNE 2018

	Note	2018 \$	2017 \$
Finance revenue		1,001,509	500,162
Other revenue		142,313	73,259
Revenue	7	1,143,822	573,421
Other income	8	2,766	1,601
Research and development expenses	9	(24,891,534)	(4,838,300)
Patent expenses		(160,836)	(171,617)
Intellectual property costs		(97,466)	(85,847)
Administrative expenses	10	(4,655,305)	(4,695,962)
Occupancy expenses	10	(104,502)	(107,921)
Gain on disposal of subsidiary		_	2,521
Net foreign exchange loss		(156,433)	(38,704)
Loss before income tax		(28,919,488)	(9,360,808)
Income tax benefit	11	12,017,248	3,167,912
Loss for the year		(16,902,240)	(6,192,896)
Other comprehensive income			
Items that may be reclassified subsequently to profit or loss:			
Unrealised gains/(losses) on available for sale assets		(354,935)	832,326
Other comprehensive income/(loss) for the period, net of tax		(354,935)	832,326
Total comprehensive loss for the period		(17,257,175)	(5,360,570)
Loss for the period is attributable to:			
Non-controlling interests		_	_
Owners of the parent	21	(16,902,240)	(6,192,896)
		(16,902,240)	(6,192,896)
Total comprehensive loss for the period is attributable to:			
Non-controlling interests		_	_
Owners of the parent		(17,257,175)	(5,360,570)
		(17,257,175)	(5,360,570)
Earnings per share for loss attributable to the ordinary equity holders of the parent:			
Basic and diluted loss per share (cents)	12	(8.38)	(3.84)

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

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION AT 30 JUNE 2018

	Note	2018 \$	2017 \$
Assets			
Current assets			
Cash and cash equivalents	13	32,510,230	51,959,906
Current tax receivable	11	12,017,248	2,709,765
Receivables	14	393,732	508,966
Prepayments		292,257	153,957
Total current assets		45,213,467	55,332,594
Non-current assets			
Available-for-sale financial assets	15	793,301	1,148,236
Plant and equipment	16	69,086	63,837
Total non-current assets		862,387	1,212,073
Total assets		46,075,854	56,544,667
Liabilities			
Current liabilities			
Payables	17	7,275,505	1,603,075
Provisions	18	459,432	399,670
Other financial liabilities		129,074	_
Total current liabilities		7,864,011	2,002,745
Non-current liabilities			
Provisions	19	38,462	24,804
Other liabilities		935	25,154
Total non-current liabilities		39,397	49,958
Total liabilities		7,903,408	2,052,703
Net assets		38,172,446	54,491,964
Equity			
Contributed equity	20	98,403,149	97,853,499
Accumulated losses	21	(65,149,999)	(48,247,759)
Reserves	21	4,919,296	4,886,224
Total equity		38,172,446	54,491,964

The above consolidated statement of financial position should be read in conjunction with the accompanying notes.

## CONSOLIDATED STATEMENT OF CHANGES IN EQUITY FOR THE YEAR ENDED 30 JUNE 2018

	Note	Contrib- uted equity \$	Options reserve	Share- based payments reserve \$	Unrealised gains reserve \$	Accumu- lated losses \$	Total equity \$
As at 1 July 2016		53,844,979	1,989,067	1,198,971	-	(42,054,863)	14,978,154
Unrealised losses on available for sale assets*	21	_	_	-	832,326	_	832,326
Loss for the year*		_	_	-	_	(6,192,896)	(6,192,896)
Total comprehensive income and expense for the period		-	-	_	832,326	(6,192,896)	(5,360,570)
Recognition of share-based payment	21	_	_	865,860	-	_	865,860
Issue of ordinary shares and share options net of share issue costs and tax	20	44,008,520	-	_	_	_	44,008,520
Balance at 30 June 2017		97,853,499	1,989,067	2,064,831	832,326	(48,247,759)	54,491,964
As at 1 July 2017		97,853,499	1,989,067	2,064,831	832,326	(48,247,759)	54,491,964
Unrealised gains on available for sale assets*	21	_	-	-	(354,935)	_	(354,935)
Loss for the year*						(16,902,240)	(16,902,240)
Total comprehensive income and expense for the period		-	-	_	(354,935)	(16,902,240)	(17,257,175)
Recognition of share-based payment	21	_	-	388,007	-	_	388,007
Issue of ordinary shares	20	549,650	_	-	-	-	549,650
Balance at 30 June 2018		98,403,149	1,989,067	2,452,838	477,391	(65,149,999)	38,172,446

<sup>\*</sup> Amounts are after tax

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

## CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE YEAR ENDED 30 JUNE 2018

	Note	2018 \$	2017 \$
Cash flows from operating activities			
Interest received		774,606	273,259
Royalty and licence income received		154,709	85,655
Sales of reagents		2,766	1,601
Payments to suppliers, employees and for research & development and intellectual property costs (inclusive of GST)		(23,579,396)	(9,049,506)
Income tax refund		2,709,765	2,643,553
Net cash flows used in operating activities	24	(19,937,550)	(6,045,438)
Cash flows from investing activities			
Cash received on disposal of subsidiary		_	171,622
Purchase of plant and equipment		(34,417)	(3,077)
Net cash flows provided by/(used in) investing activities		(34,417)	168,545
Cash flows from financing activities			
Ordinary shares issued through an entitlement offer		_	10,075,479
Ordinary shares issued through a new placement		-	35,260,371
Ordinary shares issued on exercise of options		549,650	447,969
Payment of share issue costs		-	(2,373,715)
Net cash flows provided by financing activities		549,650	43,410,104
Net increase/(decrease) in cash and cash equivalents		(19,422,317)	37,533,211
Effects of exchange rate changes on the balance of cash held in foreign currencies		(27,359)	(59,708)
Cash and cash equivalents at beginning of year		51,959,906	14,486,403
Cash and cash equivalents at the end of the year	13	32,510,230	51,959,906

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

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

#### 1. REPORTING ENTITY

Opthea Limited (the Company) is a listed public company incorporated in Australia. The address of its registered office and principal place of business is: Suite 0403, Level 4, 650 Chapel Street, South Yarra, VIC 3141, Australia. These consolidated financial statements comprise the Company and its subsidiaries (together referred to as the Group).

The Company's principal activity is the development of new drugs for the treatment of eye diseases.

#### 2. BASIS OF ACCOUNTING

These financial statements are general purpose financial statements which have been prepared in accordance with the *Corporations Act 2001*, Accounting Standards and Interpretations, and comply with other requirements of the law.

The financial statements comprise the consolidated financial statements of the Group. For the purposes of preparing the consolidated financial statements, the Company is a for-profit entity. Accounting Standards include Australian Accounting Standards

Compliance with Australian Accounting Standards ensures that the financial statements and notes of the Company and the Group comply with International Financial Reporting Standards ('IFRS').

The financial statements were authorised for issue by the directors on 28 August 2018.

## 3. SUMMARY OF ACCOUNTING POLICIES

The consolidated financial statements have been prepared using the significant accounting policies and measurement bases summarised below.

#### **Basis of measurement**

The consolidated financial statements have been prepared on a historical cost basis, except for the investments classified as available-for-sale, which have been measured at fair value. All amounts are presented in Australian dollars.

#### **Basis of consolidation**

The consolidated financial statements incorporate the financial statements of the Company and entities controlled by the Company and its subsidiaries. Control is achieved when the Company:

- / Has power over the investee;
- Is exposed, or has rights, to variable returns from its involvement with the investee; and
- / Has the ability to use its power to affect its returns.

The Company reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control listed above.

When the Company has less than a majority of the voting rights of an investee, it has power over the investee when the voting rights are sufficient to give it the practical ability to direct the relevant activities of the investee unilaterally. The Company considers all relevant facts and circumstances in assessing whether or not the Company's voting rights in an investee are sufficient to give it power, including:

- The size of the Company's holding of voting rights relative to the size and dispersion of holdings of the other vote holders;
- Potential voting rights held by the Company, other vote holders or other parties;
- Rights arising from other contractual arrangements; and
- Any additional facts and circumstances that indicate that the Company has, or does not have, the current ability to direct the relevant activities at the time that decisions need to be made, including voting patterns at previous shareholders' meetings.

Consolidation of a subsidiary begins when the Company obtains control over the subsidiary and ceases when the Company loses control of the subsidiary. Specifically, income and expenses of a subsidiary acquired or disposed of during the year are included in the consolidated statement of profit or loss and other comprehensive income from the date the Company gains control until the date when the Company ceases to control the subsidiary.

Profit or loss and each component of other comprehensive income are attributed to the owners of the Company and to the non-controlling interests. Total comprehensive income of subsidiaries is attributed to the owners of the Company and to the non-controlling interests even if this results in the non-controlling interests having a deficit balance.

When necessary, adjustments are made to the financial statements of subsidiaries to bring their accounting policies into line with the Group's accounting policies.

All intragroup assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONT.)

#### Foreign currency translation

#### i. Functional and presentation currency

Both the functional and presentation currency of Opthea Limited and its Australian subsidiaries is Australian dollars (\$).

#### ii. Transactions and balances

Transactions in foreign currencies are initially recorded in the functional currency by applying the exchange rates ruling at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies are retranslated at the rate of exchange ruling at the reporting date.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rate as at the date of the initial transaction. Non-monetary items measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was determined.

#### Cash and cash equivalents

Cash and cash equivalents in the statement of financial position comprise cash at bank and in hand and short-term deposits with an original maturity of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.

For the purposes of the statement of cash flows, cash and cash equivalents consist of cash and cash equivalents as defined above.

#### **Current receivables**

Receivables generally comprise bank interest receivable, other receivable from external parties and GST credits receivable, and are recognised and carried at original invoice amount less an allowance for any uncollectible amounts. The amounts are usually received within 30-60 days of recognition.

Collectability of receivables is reviewed on an ongoing basis. Debts that are known to be uncollectible are written off when identified. An impairment provision is recognised when there is objective evidence that the Group will not be able to collect the receivable.

#### Investments and other financial assets

Investments and financial assets are classified as available-for-sale investments, or loans and receivables as appropriate, in accordance with AASB 139 Financial Instruments: Recognition and Measurement. The classification depends on the purpose for which the investments were acquired or originated. Designation is re-evaluated at each reporting date, but there are restrictions on reclassifying to other categories.

When financial assets are recognised initially, they are measured at fair value, plus, in the case of assets not at fair value through profit or loss, directly attributable transaction costs.

#### Recognition and derecognition

Purchases and sales of financial assets that require delivery of assets within the time frame generally established by regulation or convention in the market place are recognised on the trade date i.e. the date that the Group commits to purchase the asset. Financial assets are derecognised when the right to receive cash flows from the financial assets has expired or when the entity transfers substantially all the risks and rewards of the financial assets. If the entity neither retains nor transfers substantially all of the risks and rewards, it derecognises the asset if it has transferred control of the assets.

#### Subsequent measurement

#### i. Available-for-sale investments

Available-for-sale investments comprise of the Group's non-current investments in listed companies. After initial recognition, available-for-sale investments are measured at fair value with gains or losses being recognised as a separate component of equity until the investment is sold, collected or otherwise disposed of, or until the investment is determined to be impaired, at which time the cumulative gain or loss previously reported in equity is recognised in profit or loss.

The fair values of available-for-sale investments that are actively traded in organised financial markets is determined by reference to quoted market bid prices at the close of business on the reporting date.

#### ii. Loans and receivables

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. Such assets are carried at amortised cost using the effective interest method and have been calculated by discounting the principal amounts over the relevant term using the relevant LIBOR rate which matches that term as closely as possible. Gains and losses are recognised in the statement of comprehensive income when the loans and receivables are derecognised or impaired. These are included in current assets, except for those with maturities greater than 12 months after balance date, which are classified as non-current.

Non-current receivables comprise loans receivable from subsidiaries which are not interest bearing. The parent has agreed that the loans with its subsidiaries will not be recalled for a period of 12 months from the date the directors adopt the relevant annual financial statements of the Group, parent and subsidiaries.

#### Impairment of financial assets

The Group assesses at each reporting date whether a financial asset or group of financial assets is impaired.

#### i. Available-for-sale investments

If there is objective evidence (i.e. significant or prolonged decline in quoted market bid prices) that an available-for-sale investment is impaired, an amount comprising of the difference between its cost and its current fair value, less any impairment loss previously recognised in profit or loss is transferred from equity to profit or loss. Reversals of impairment losses for equity instruments classified as available-for-sale are not recognised.

#### ii. Financial assets carried at amortised cost

Loans receivable from subsidiaries in the parent's accounts are financial assets carried at amortised cost. If there is objective evidence that an impairment loss on intercompany loans receivable carried at amortised cost has been incurred, the amount of the loss is measured as the difference between the asset's carrying amount and the present value of estimated future cash flows (excluding future credit losses that have not been incurred) discounted at the financial asset's original effective interest rate (i.e. the effective interest rate computed at initial recognition). The carrying amount of the asset is reduced either directly or through use of an allowance account. The amount of the loss is recognised in the statement of comprehensive income.

The Group firstly assesses whether objective evidence of impairment exists individually for financial assets that are individually significant, and secondly individually or collectively for financial assets that are not individually significant. If it is determined that no objective evidence of impairment exists for an individually assessed financial asset, whether significant or not, the asset is included in a group financial assets with similar credit risk characteristics and that group of financial assets is collectively assessed for impairment. Assets that are individually assessed for impairment and for which an impairment loss is or continues to be recognised are not included in a collective assessment of impairment.

If, in a subsequent period, the amount of the cumulative impairment loss decreases and the decreases can be related objectively to an event occurring after the impairment was recognised, the previously recognised impairment loss is reversed. Any subsequent reversal of an impairment loss is recognised in profit or loss, to the extent that the carrying value of the asset does not exceed its amortised cost at the reversal date.

#### Investments in subsidiaries

Investments in subsidiaries are carried at cost. If there is objective evidence that an impairment loss has been incurred on investments in subsidiaries, the amount of the loss is measured as the difference between the asset's carrying amount and the present value of estimated future cash flows, discounted at the current market rate of return for a similar financial asset. Any subsequent reversal of an impairment loss is recognised in profit or loss.

#### Plant and equipment

Plant and equipment is stated at historical cost less accumulated depreciation and any accumulated impairment losses. Depreciation is calculated on a straight-line basis over their useful economic lives as follows:

- / Equipment and furniture 3 to 10 years
- / Leasehold improvements 8 years

The assets' residual values, useful lives and amortisation methods are reviewed, and adjusted if appropriate, at each financial year end.

#### **Derecognition**

An item of plant and equipment is derecognised upon disposal or when no further economic benefits are expected from its use or disposal.

#### Leases

The determination of whether an arrangement is or contains a lease is based on the substance of the arrangement and requires an assessment of whether the fulfilment of the arrangement is dependent on the use of a specific asset or assets and the arrangement conveys a right to use the asset, even if that right is not explicitly specified in an arrangement.

Operating lease payments are recognised as an expense in profit or loss on a straight-line basis over the lease term. Operating lease incentives are recognised in the statement of comprehensive income as an integral part of the total lease expense.

The Group held no finance leases during the 2018 and 2017 financial years.

#### Impairment of non-financial assets other than goodwill

Non-financial assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. For the policy relating to impairment regarding investments in associates, see note above.

Opthea Limited conducts an annual internal review of asset values, which is used as a source of information to assess for any indicators of impairment. External factors, such as changes in technology and economic conditions, are also monitored to assess for indicators of impairment. If any indication of impairment exists, an estimate of the asset's recoverable amount is calculated.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONT.)

An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount. Recoverable amount is the higher of an asset's fair value less costs to sell and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash inflows that are largely independent of the cash inflow from other assets or groups of assets (cash-generating units). Non-financial assets other than goodwill that suffered impairment are tested for possible reversal of the impairment whenever events or changes in circumstances indicate that the impairment may have reversed.

#### Intangible assets

Internally generated intangible assets are not capitalised and expenditure is charged against profits in the year in which the expenditure is incurred.

#### Intellectual property costs

Amounts incurred for rights to or for acquisition of intellectual property are expensed in the year in which they are incurred to the extent that such intellectual property is used for research and development activities.

#### Research and development costs

Research costs are expensed as incurred. An intangible asset arising from the development expenditure on an internal project will only be recognised when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the development and the ability to measure reliably the expenditure attributable to the intangible asset during its development. Following the initial recognition of the development expenditure, the cost model is applied requiring the asset to be carried at cost less any accumulated amortisation and accumulated impairment losses. Any expenditure so capitalised is amortised over the period of expected benefits from the related project.

The carrying value of an intangible asset arising from development expenditure is tested for impairment annually when the asset is not yet available for use or more frequently when an indication of impairment arises during the reporting period.

#### **Payables**

Payables are carried at amortised cost and due to their short term nature, they are not discounted. They represent liabilities for goods and services provided to the Group prior to the end of the financial year that are unpaid and arise when the Group becomes obliged to make future payments in respect of the purchase of these goods and services.

The amounts are unsecured and are usually paid within 30 days of recognition.

#### **Provisions and employee benefits**

#### i. Wages, salaries, annual leave and sick leave

Liabilities for wages and salaries, including non-monetary benefits and annual leave expected to be settled within 12 months of the reporting date are recognised in current provisions in respect of employees' services up to the reporting date. They are measured at the amounts expected to be paid when the liabilities are settled. Expenses for non-accumulating sick leave are recognised when the leave is taken and are measured at the rate paid or payable.

#### ii. Long service leave

The liability for long service leave is recognised in the provision for employee benefits and measured as the present value of expected future payments to be made in respect of services provided by employees up to the reporting date. Consideration is given to expected future wage and salary levels, experience of employee departures, and periods of service. Expected future payments are discounted using market yields at the reporting date on national government bonds with terms to maturity that match, as closely as possible, the estimated future cash outflows.

#### Share-based payment transactions

The Group provides benefits to directors and employees (including key management personnel) of the Group in the form of share based payments, whereby employees render services in exchange for shares or rights over shares (equity-settled transactions).

The cost of these equity-settled transactions with employees is measured by reference to the fair value at the date at which they are granted. Binomial models are used to value the options issued.

The cost of the equity-settled transactions is recognised, together with a corresponding increase in equity, over the period in which the performance conditions are fulfilled (the vesting period), ending on the date on which the relevant employees become fully entitled to the award (the vesting date).

At each subsequent report date until vesting, the cumulative charge to profit or loss is the product of:

- i. the grant date fair value of the award;
- ii. the current best estimate of the number of awards that will vest, taking into account such factors as the likelihood of employee turnover during the vesting period; and
- iii. the expired portion of the vesting period.

The charge to profit or loss for the period is the cumulative amount as calculated above less the amounts already charged in previous periods. There is a corresponding credit to equity.

Until an award has vested, any amounts recorded are contingent and will be adjusted if more or fewer awards vest than were originally anticipated to do so. Any award subject to a market condition is considered to vest irrespective of whether or not that market condition is fulfilled, provided that all other conditions are met.

Where the terms of the equity-settled award are modified, as a minimum an expense is recognised as if the terms had not been modified. An additional expense is recognised for any modification that increases the total fair value of the share-based payment arrangement, or is otherwise beneficial to the employee, as measured at the date of modification.

The dilutive effect, if any, of outstanding options is reflected as additional share dilution in the computation of earnings per share. There is, however no dilutive effect when there is a loss per share.

#### **Contributed equity**

Ordinary shares are classified as equity. Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction, net of tax, from the proceeds.

#### Revenue recognition

Revenue is recognised and measured at the fair value of the consideration received or receivable to the extent that it is probable that the economic benefits will flow to the Group and the revenue can be reliably measured. The following specific recognition criteria must also be met before revenue is recognised:

#### i. Interest revenue

Almost all of the Group's interest revenue is earned on short-term bank deposits and as such interest revenue is recognised when the Group's right to receive the payment is established.

#### ii. Royalty fee and licence fee revenue

Royalty fee and licence fee revenue is recognised when earned.

#### Income tax

Current tax assets and liabilities for the current and prior periods are measured at the amount expected to be recovered from or paid to the taxation authorities based on the current period's taxable income. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted by the reporting date.

Deferred income tax is provided on all temporary differences at the reporting date between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

Deferred income tax liabilities are recognised for all taxable temporary differences except:

- when the deferred income tax liability arises from the initial recognition of goodwill or of an asset or liability in a transaction that is not a business combination and that, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; or
- / when the taxable temporary difference is associated with investments in subsidiaries, associate or interests in joint ventures, and the timing of the reversal of the temporary difference can be controlled and it is probable that the temporary difference will not reverse in the foreseeable future.

Deferred income tax assets are recognised for all deductible temporary differences, carry forward of unused tax assets (or credits) and unused tax losses, to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carry forward of unused tax credits and unused tax losses can be utilised, except:

- / when the deferred income tax asset relating to the deductible temporary differences arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit or taxable profit or loss; or
- / when the deductible temporary difference is associated with investments in subsidiaries, associates or interests in joint ventures, in which case a deferred tax asset is only recognised to the extent that it is probable that the temporary difference will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilised.

The carrying amount of deferred income tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred income tax asset to be utilised.

Unrecognised deferred income tax assets are reassessed at each reporting date and are recognised to the extent that it has become probable that future taxable profit will allow the deferred tax asset to be recovered.

Deferred income tax assets and liabilities are measured at the tax rates that are expected to apply to the year when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at balance date.

Income taxes relating to items recognised directly in equity are recognised directly in equity and not in profit or loss.

#### Tax consolidation legislation

The head entity, Opthea Limited, and the controlled entities in the tax consolidated group account for their own current and deferred tax amounts. Members of the tax consolidated group have adopted the "separate taxpayer within group" method to allocate the current and deferred tax amounts to each entity within the Group. This method requires adjustments for transactions and events occurring within the tax consolidated group that do not give rise to a tax consequence for the Group or that have a different tax consequence at the level of the Group.

In addition to its own current and deferred tax amounts, Opthea Limited also recognises the current tax liabilities (or assets) and the deferred tax assets arising from unused tax losses and unused tax credits assumed from controlled entities in the tax consolidated group.

The head entity, which is the parent entity, in assuming the net unused tax losses and unused relevant tax credits, has recognised reductions to investments in subsidiaries and where the amount of tax losses assumed is in excess of the carrying value of the investment, the parent has recognised the difference as a distribution from subsidiary in profit or loss.

#### Other taxes

Revenues, expenses, assets and liabilities are recognised net of the amount of GST except:

- / when the GST incurred on a purchase of goods and services is not recoverable from the taxation authority, in which case the GST is recognised as part of the cost of acquisition of the asset or as part of the expense item as applicable; and
- / receivables and payables are stated with the amount of GST included.

The net amount of GST recoverable from, or payable to the taxation authority is included as part of receivables or payables in the statement of financial position.

Cash flows are included in the statement of cash flows on a gross basis and the GST component of cash flows arising from investing and financing activities, which is recoverable from, or payable to, the taxation authority is classified as part of operating cash flows.

Commitments and contingencies are disclosed net of the amount of GST recoverable from, or payable to, the taxation authority.

#### Government grants

Government grants are recognised when there is reasonable assurance that the grant will be received and all attaching conditions will be complied with.

When the grant relates to an expense item, it is recognised as income over the periods necessary to match the grant on a systematic basis to the costs that it is intended to compensate. They are not credited directly to shareholders equity.

#### Earnings per share

Diluted earnings per share is calculated as net profit/loss divided by the weighted average number of ordinary shares and dilutive potential ordinary shares. Whilst the deferred shares would generally be included in the calculation as their conditions of issuance are known to be satisfied, due to there being a loss for the current year, these instruments would be anti-dilutive (decrease the loss per share). Accordingly they have been excluded from the calculation, resulting in basic earnings/(loss) per share being the same as the diluted value per share.

#### Comparatives

Where necessary, comparatives have been reclassified and repositioned for consistency with current year disclosure.

### 4. CRITICAL ACCOUNTING JUDGEMENTS AND KEY SOURCES OF ESTIMATION UNCERTAINTY

In applying the Group's accounting policies, management continually evaluates judgements, estimates and assumptions based on experience and other factors, including expectations of future events that may have an impact on the Group. All judgements, estimates and assumptions made are believed to be reasonable based on the most current set of circumstances available to management. Actual results may differ from the judgements, estimates and assumptions.

Significant judgements, estimates and assumptions made by management in the preparation of these financial statements are outlined below:

#### 4.1 Critical judgements in applying accounting policies

#### Research and development costs

The majority of Opthea's expenditure is incurred as a result of clinical trials for OPT-302. During the 2018 financial year, Opthea has progressed Phase 2b wet AMD and Phase 1b/2a DME studies. A key measure of Opthea's performance is the level of expenditure incurred on the research of OPT-302. The authorisation and classification of expenses requires judgement as the cash assets of the Group are primarily expended in the research of OPT-302. The Company has controls in place to ensure expenses are:

- / correctly classified and disclosed, and
- / appropriately approved.

#### Capitalised development costs

Development costs are only capitalised by the Group when it can be demonstrated that the technical feasibility of completing the intangible asset is valid so that the asset will be available for use or sale.

No development costs were capitalised during the current year.

#### Impairment of available-for-sale assets

The Group holds available-for-sale financial assets and follows the requirements of AASB 139 Financial Instruments: Recognition and Measurement in determining when an available-for-sale asset is impaired. For the year ended 30 June 2018, no impairments (2017: \$nil) have been recognised for available-for-sale financial assets.

#### **Taxation**

The Group's accounting policy for taxation requires management judgements as to the types of arrangements considered to be a tax on income in contrast to an operating cost. Judgement is also required in assessing whether deferred tax assets and certain deferred tax liabilities are recognised in the statement of financial position. Deferred tax assets, including those arising from unrecouped tax losses.

Judgements are also required about the application of income tax legislation. These judgements and assumptions are subject to risk and uncertainty, hence there is a possibility that changes in circumstances will alter expectations, which may impact the amount of deferred tax assets and deferred tax liabilities recognised in the statement of financial position and the amount of other tax losses and temporary differences not yet recognised. In such circumstances, some or all of the carrying amounts of recognised deferred tax assets and liabilities may require adjustment, resulting in a corresponding credit or charge to profit or loss.

#### 4.2 Key sources of estimation uncertainty

#### Valuation of investments

The Group has classified investments in listed securities as 'available-for-sale' investments and movements in fair value are recognised directly in equity, unless considered impaired. The fair value of listed shares has been determined by reference to published price quotations in an active market.

#### Share-based payment transactions

The Group measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. Fair values are determined internally using Binomial models. The related assumptions are detailed in note 28. The accounting estimates and assumptions relating to equity-settled share-based payments have no impact on the carrying amounts of assets and liabilities in future reporting periods but may impact expenses and equity.

### 5. APPLICATION OF NEW AND REVISED ACCOUNTING STANDARDS

Amendments to AASBs and the new interpretation that are mandatorily effective for the current year 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 its operations and effective for the current year.

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

- / AASB 1048 Interpretation of Standards;
- AASB 2016-1 Amendments to Australian Accounting Standards – Recognition of Deferred Tax Assets for Unrealised Losses;
- / AASB 2016-2 Amendments to Australian Accounting Standards – Disclosure Initiative: Amendments to AASB 107;
- AASB 2017-2 Amendments to Australian Accounting Standards – Further Annual Improvements 2014-2016.

### Impact of the application of AASB 1048 Interpretation of Standards

The application of these amendments has had no impact on the Group's consolidated financial statements as this is a service standard that ensures there is no difference between the status of Interpretations in the hierarchy between IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors and AASB 108 Accounting Policies, Changes in Accounting Estimates and Errors.

### Impact of the application of AASB 2016-1 Amendments to Australian Accounting Standards – Recognition of Deferred Tax Assets for Unrealised Losses

The application of these amendments has had no impact on the Group's consolidated financial statements as the Group already assesses the sufficiency of future taxable profits in a way that is consistent with these amendments.

### Impact of the application of AASB 2016-2 Amendments to Australian Accounting Standards – Disclosure Initiative: Amendments to AASB 107

The application of these amendments has had no impact 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 as none of the Group's interests in these entities are classified, or included in a disposal group that is classified, as held for sale.

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

#### AASB 9 Financial Instruments

In July 2014, the International Accounting Standards Board issued the final version of AASB 9 Financial Instruments.

IFRS 9 is effective for annual periods beginning on or after 1 January 2018, with early adoption permitted. The Group currently plans to apply AASB 9 on 1 July 2018.

The Group has performed a preliminary assessment of the potential impact of the adoption of AASB 9 based on its positions at 30 June 2018.

#### Classification - Financial assets

AASB 9 contains a new classification and measurement approach for financial assets that reflects the business model in which assets are managed and their cash flow characteristics.

AASB 9 contains three principal classification categories for financial assets: measured at amortised cost, fair value through other comprehensive income (FVOCI) and fair value through profit or loss (FVTPL). The standard eliminates the existing IAS 39 categories of held to maturity, loans and receivables and available for sale.

Based on its preliminary assessment, the Group does not believe that the new classification requirements, if applied at 30 June 2018, would have had a material impact on its accounting for receivables and investments in equity securities that are managed on a fair value basis.

At 30 June 2018, the Group had equity investments classified as available-for-sale with a fair value of \$793,301 (2017: \$1,148,236) that are held for long-term strategic purposes.

If these investments continue to be held for the same purpose at initial application of AASB 9, the Group may elect then to classify them as FVOCI or FVTPL. The Group has not yet made a decision in this regard.

#### Transition

The Group plans to take advantage of the exemption allowing it not to restate comparative information for prior periods with respect to classification and measurement (including impairment) changes. Differences in the carrying amounts of financial assets and financial liabilities resulting from the adoption of IFRS 9 generally will be recognised in retained earnings and reserves as at 1 July 2018.

#### AASB 15 Revenue from Contracts with Customers

AASB 15 establishes a comprehensive framework for determining whether, how much and when revenue is recognised. It replaces existing revenue recognition guidance, including AASB 118 Revenue. AASB 15 is effective for annual periods beginning on or after 1 January 2018, with early adoption permitted.

The Group has completed an initial assessment of the potential impact of the adoption of AASB 15 on its consolidated financial statements. The Group earned royalties and licence fees of \$142,313 (2017: \$73,259) from its intellectual property portfolio during the year. The amount disclosed in the accounts would not be materially affected if AASB 15 were applied in the 2018 financial year.

The Group plans to adopt AASB 15 in its consolidated financial statements for the year ending 30 June 2019, using the retrospective approach. As a result, the Group will apply all of the requirements of AASB 15 to each comparative period presented and adjust its consolidated financial statements. The Group is currently performing a detailed assessment of the impact resulting from the application of AASB 15.

#### **AASB 16 Leases**

AASB 16 introduces a single, on-balance lease sheet accounting model for lessees. A lessee recognises a right-of-use asset representing its right to use the underlying asset and a lease liability representing its obligation to make lease payments. There are optional exemptions for short-term leases and leases of low value items.

The standard is effective for annual periods beginning on or after 1 January 2019. The Group currently plans to apply IFRS 16 initially on 1 July 2019. The Group has started an initial assessment of the potential impact on its consolidated financial statements. The amounts disclosed in the accounts would not be materially different if IFRS 16 were applied in the 2018 financial year.

The most significant impact identified is that the Group will recognise new assets and liabilities for its operating leases of office facilities. In addition, the nature of expenses related to those leases will now change as AASB 16 replaces the straight-line operating lease expense with a depreciation charge for right-of-use assets and interest expense on lease liabilities.

#### Transition

As a lessee, the Group can either apply the standard using a:

- / Retrospective approach; or
- Modified retrospective approach with optional practical expedients.

The Group has not yet determined which transition approach to apply.

#### Other amendments

The following new or amended standards are not expected to have a significant impact on the Group's consolidated financial statements.

- AASB 2016-5 Amendments to Australian Accounting Standards – Classification and Measurement of Share-based Payment Transactions;
- AASB 2014-10 Amendments to Australian Accounting Standards – Sale or Contribution of Assets between an Investor and its Associate or Joint Venture;
- AASB 2017-2 Amendments to Australian Accounting Standards – Transfers of Investment Property, Annual Improvements 2014-2016 Cycle and Other Amendments
- AASB 2017-6 Amendment to Australian Accounting Standards
   Prepayment Features with Negative Compensation
- AASB 2017-7 Amendments to Australian Accounting Standards – Long-term Interests in Associates and Joint Ventures
- AASB 2008-1 Amendments to Australian Accounting Standards
   Annual Improvements 2015–2017 Cycle AASB 2008-1
   Amendments to Australian Accounting Standards Annual Improvements 2015–2017 Cycle
- / AASB 2008-2 Amendments to Australian Accounting Standards – Plan Amendment, Curtailment or Settlement
- Interpretation 22 Foreign Currency Transactions and Advance Consideration
- / Interpretation 23 Uncertainty over Income Tax Treatments
- / Amendment to References to the Conceptual Framework in IFRS Standards

#### 6. SEGMENT INFORMATION

The Group operates in one industry and one geographical segment, those being the medical technology and healthcare industry and Australia respectively.

The Group is a biologics drug developer building on its significant intellectual property portfolio around Vascular Endothelial Growth Factor (VEGF) C and D (angiogenic molecules) and R3. The Group is focused primarily on developing biological therapeutics for eye diseases.

The chief executive officer regularly reviews entity wide information that is compliant with Australian Accounting Standards. There is only one segment for segment reporting purposes and the information reviewed by the chief executive officer is the same as the information presented in the financial statements.

#### 7. REVENUE

	2018 \$	2017 \$
(a) Finance revenue		
Interest from:		
- Bank	1,001,509	500,162
	1,001,509	500,162
(b) Other revenue		
Royalties and licence fees	142,313	73,259
Total revenue	1,143,822	573,421

#### 8. OTHER INCOME

	2018 \$	2017 \$
Other	2,766	1,601
Total other income	2,766	1,601

#### 9. RESEARCH AND DEVELOPMENT EXPENSES

	2018 \$	2017 \$
Research project costs <sup>1</sup>	24,891,534	4,838,300
Total research and development expenses	24,891,534	4,838,300

<sup>1</sup> The research project costs relate to the development programs in respect to the treatment of eye diseases by OPT-302.

#### 10. EXPENSES

	2018	2017 \$
(a) Impairment losses		
Listed financial investments	-	_
(b) Occupancy expenses		
Operating lease rentals	78,199	78,199
Outgoings	26,303	29,722
Total occupancy expense	104,502	107,921
(c) Administrative expenses		
Depreciation of:		
Equipment and furniture	15,461	13,420
Leasehold improvements	13,194	13,194
Total depreciation expense	28,655	26,614
Loss on disposal of non-current assets	513	3,776
Employee benefits expenses:		
Salaries and fees	1,925,671	1,788,441
Cash bonuses	372,284	545,946
Superannuation	204,927	199,953
Share-based payments expense	388,007	865,860
Total employee benefits expense	2,890,889	3,400,200
Other expenses:		
Travel expenses	69,528	85,046
Insurance	270,491	158,892
Consultancy fees	29,784	11,250
Legal fees	40,116	78,810
Payroll tax	88,502	92,225
Investor relations costs	353,287	401,673
Audit and accounting	168,222	137,425
Other expenses	715,318	300,051
Total other expenses	1,735,248	1,265,372
Total administrative expenses	4,655,305	4,695,962

#### 11. INCOME TAX

	2018 \$	2017 \$
(a) Income tax benefit		
The major components of income tax benefit are:		
Statement of Comprehensive Income		
Current tax		
Current income tax credit	11,793,345	2,709,765
Under recognition of prior year benefit <sup>1</sup>	223,903	1,056,563
	12,017,248	3,766,328
Deferred tax		
In respect of the current year	_	(598,416
Total income tax benefit recognised in the statement of comprehensive income	12,017,248	3,167,912
1 Relates to under recognition of R&D Tax incentive for the 2017 and 2016 financial years. The Company re finding application during the 2017 financial year which then allowed it to include overseas expenditure in		ts advance
(b) Amounts charged or credited directly to equity		
Deferred income tax related to items credited directly to equity		
Share issue expenses deductible over 5 years	-	598,416
Income tax benefit reported in equity	-	598,416
(c) Current tax receivable		
Research and Development Tax Incentive Credit receivable	12.017.248	2,709,765

### (d) Numerical reconciliation between aggregate tax expense recognised in the statement of comprehensive income and expense calculated per the statutory income tax rate

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

	2018 \$	2017 \$
Accounting loss before tax	(28,919,488)	(9,360,808)
At the parent entity's statutory income tax rate of 27.5% (2017: 30%)	7,952,859	2,808,242
Research and development tax credit refundable	11,793,345	2,709,765
Write off of temporary differences and tax losses not recovered	(7,505,053)	(1,293,532)
Adjustments recognised in current year in relation to the current tax of prior year	(223,903)	(1,056,563)
Income tax benefit reported in the statement of comprehensive income	12,017,248	3,167,912

#### 11. INCOME TAX (CONT.)

TI. INCOME TAX (CONI.)	2018 \$	2017 \$
(e) Recognised deferred tax assets and liabilities in statement of financial position		
Deferred income tax at 30 June relates to the following:		
Deferred tax liabilities:		
Interest and royalty income receivable (future assessable income)	(95,043)	(160,927)
	(95,043)	(160,927)
Deferred tax assets:		
Other timing differences including income received in advance	230,803	196,078
Employee provisions	149,368	127,342
Temporary differences:		
Associated with other miscellaneous items	540,840	777,757
	921,011	1,101,177
Less: temporary differences not recognised	(825,968)	(940,251)
Net deferred tax recognised in the statement of financial position	_	_

#### (f) Unrecognised temporary differences

Temporary differences with respect to deferred tax assets associated with intellectual property and other miscellaneous items which have a low probability of realisation are unrecognised. These amounted to \$825,968 at year end (2017: \$940,251).

#### (g) Tax consolidation

#### (i) Members of the tax consolidated group

Opthea Limited and its 100% owned subsidiaries formed a tax consolidated group effective 1 July 2003. Opthea Limited is the head entity of the tax consolidated group.

#### (ii) Tax effect accounting by members of the tax consolidated group

Members of the tax consolidated group have adopted the "separate taxpayer within group" method to allocate the current and deferred tax amounts to each entity within the group.

#### (h) Carry forward unrecognised tax losses

The Group had income tax losses of \$15,196,881 and capital losses of \$877,704 at year end (2017: income tax losses of \$14,427,258 and capital losses of \$877,704) for which no deferred tax asset is recognised on the statement of financial position as they are currently not considered probable of realisation. These tax losses are available indefinitely for offset against future assessable income subject to continuing to meet relevant statutory tests.

#### (i) Franking credit balance

The franking account balance at the end of the financial year at 30% is \$330,630 (2017: \$330,630), which represents the amount of franking credits available for the subsequent financial year.

#### 12. EARNINGS PER SHARE

	2018 \$	2017 \$
The following reflects the income used in the basic and diluted earnings per share computations:		
(a) Earnings used in calculating earnings per share		
Net loss attributable to ordinary equity holders of the parent	(16,902,240)	(6,192,896)
(b) Weighted average number of shares		
Weighted average number of ordinary shares on issue for basic earnings per share	201,580,604	161,229,036
Effect of dilution:		
Share options	_	_
Weighted average number of ordinary shares adjusted for the effect of dilution	201,580,604	161,229,036

There have been no other transactions involving ordinary shares or potential ordinary shares that would significantly change the number of ordinary shares or potential ordinary shares outstanding between the reporting date and the date of completion of this financial report.

Diluted earnings per share is calculated as net profit/(loss) divided by the weighted average number of ordinary shares and dilutive potential ordinary shares. Although the options granted under the LTIP and NED Plan would generally be included in the calculation due to the conditions of the issuance being satisfied, because there is a loss in the current year, these instruments would be anti-dilutive (decrease the loss per share) and therefore have been excluded from the calculation. Therefore, the basic loss per share is the same as the diluted value per share.

#### 13. CURRENT ASSETS - CASH AND CASH EQUIVALENTS

	2018 \$	2017 \$
Cash at bank and in hand	3,010,230	2,459,906
Short-term deposits	29,500,000	49,500,000
Total cash and cash equivalents	32,510,230	51,959,906

Cash at bank earns interest at floating rates based on daily bank deposit rates. The carrying amounts of cash and cash equivalents represent fair value.

Short term-deposits are with a major bank 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 year end, the average rate was 2.55% (2017: 2.54%).

#### 14. CURRENT ASSETS - RECEIVABLES

	2018 \$	2017 \$
Interest receivable	163,700	246,118
GST receivable (1)	119,758	199,319
Other (i)	110,274	63,529
Total current receivables	393,732	508,966

<sup>(</sup>i) These receivables are non-interest bearing, most of which have repayment terms between 30 and 60 days. There are no receivables past due or considered impaired.

#### 15. NON-CURRENT ASSETS - AVAILABLE-FOR-SALE FINANCIAL ASSETS

	2018	2017
	\$	\$
Listed Australian shares – at fair value	793,301	1,148,236

#### **Details of listed Australian shares**

	Ownership Interest Fair value <sup>1</sup>		Ownership Interest Fair value <sup>1</sup>		Cost of in	vestment
Listed investments	2018 %	2017 %	2018 \$	2017 \$	2018 \$	2017 \$
Non-current investments 2:						
Antisense Therapeutics Ltd	2.74%	6.31%	254,766	336,291	3,106,944	3,106,944
Optiscan Imaging Limited	1.92%	2.20%	538,535	811,945	786,131	786,131
Total listed investments			793,301	1,148,236	3,893,075	3,893,075

<sup>1</sup> The fair value represents the share (bid) price at year 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 139 Financial Instruments: Recognition and Measurement.

These non-current investments in listed shares consist of investments in ordinary shares, and therefore have no fixed maturity date or coupon rate.

All available-for-sale investments listed above are level 1 financial assets in the fair value hierarchy. The valuation technique used to determine fair

2 A fair value decrease of \$354,935 in the carrying value of investments (2017: increase of \$832,326) has been made through other comprehensive income in the year due to a decrease in their market value in the year.

Details of the investments in subsidiaries are shown in note 23.

value is the reference to quoted bid prices in an open market.

#### 16. NON-CURRENT ASSETS - PLANT AND EQUIPMENT

	2018 \$	2017 \$
Equipment and furniture at cost		
Opening balance	74,454	175,457
Additions	34,417	3,077
Disposals	(1,538)	(104,080)
Closing balance	107,333	74,454
Accumulated depreciation		
Opening balance	(37,519)	(124,403)
Depreciation for the year	(15,461)	(13,420)
Disposals	1,025	100,304
Closing balance	(51,955)	(37,519)
Net carrying amount	55,378	36,935
Leasehold improvements at cost		
Opening balance	79,165	79,165
Closing balance	79,165	79,165
Accumulated depreciation		
Opening balance	(52,263)	(39,069)
Depreciation for the year	(13,194)	(13,194)
Disposals	-	_
Closing balance	(65,457)	(52,263)
Net carrying amount	13,708	26,902
Total plant and equipment, net	69,086	63,837

#### 17. CURRENT LIABILITIES - PAYABLES

	2018 \$	2017 \$
Creditors (unsecured) 1	7,223,010	1,555,773
PAYG tax liability	52,495	47,302
Total current payables	7,275,505	1,603,075

<sup>1</sup> Creditors are non-interest bearing and are normally settled on 30 day terms.

#### 18. CURRENT LIABILITIES - PROVISIONS

	2018 \$	2017 \$
Annual leave	293,709	253,559
Long service leave	165,723	146,111
Total current provisions	459,432	399,670

#### 19. NON-CURRENT LIABILITIES - PROVISIONS

	2018 \$	2017 \$
Long service leave	38,462	24,804

#### 20. CONTRIBUTED EQUITY

	2018 \$	2017 \$
(a) Ordinary shares		
Issued and fully paid at 30 June	98,403,149	97,853,499
Movement in ordinary shares:		
Opening balance	97,853,499	53,844,979
Issue of shares	549,650	45,783,819
Share issue costs	_	(2,373,715)
Income tax relating to share issue costs	-	598,416
	98,403,149	97,853,499
Ordinary shares on issue:	No:	No:
Opening balance	200,574,370	150,205,903
Issue of shares on exercise of LTIP and NED plan options	1,063,518	50,000
Issue of shares	_	50,318,467
	201,637,888	200,574,370

Fully paid ordinary shares carry one vote per share and carry the right to dividends.

Issued capital at 30 June 2018 amounted to \$98,403,149 (201,637,888 fully paid ordinary shares) net of share issue costs, tax and amounts taken to the options reserve. At 30 June 2018, the company had on issue quoted options to purchase 47,073,324 ordinary shares with an exercise price of \$0.27 expiring on 25 November 2018. The fair value of the options at their issue date of \$1,989,067 has been recognised in the options reserve (note 21).

During the year, the company converted 1,063,518 quoted options to ordinary fully paid shares for \$287,150. Bell Potter Securities exercised all of its 1,000,000 options and converted these to ordinary fully paid shares for \$262,500.

#### 20. CONTRIBUTED EQUITY (CONT.)

#### Share options

The company has two share based-payment schemes, the Long Term Incentive Plan (LTIP) and Non-Executive Director Share and Option Plan. Options to subscribe for the Company's shares have been granted under these plans to certain employees and directors. The company issued 9,725,000 share options over ordinary shares under these plans during 2016; 500,000 were issued under the LTIP during the current year. These share options had a weighted average fair value at their grant date of \$0.21 per share option.

#### (b) Capital management

The Group is not subject to any externally imposed capital requirements.

When managing share capital, management's objective is to ensure the entity continues as a going concern as well as to provide benefits to shareholders and for other stakeholders. In order to maintain or achieve an appropriate capital structure, the Company may issue new shares or reduce its share capital, subject to the provisions of the Company's constitution.

#### 21. RETAINED EARNINGS AND RESERVES

	2018 \$	2017 \$
(a) Movements in retained earnings were as follows:		
Balance at 1 July	(48,247,759)	(42,054,863)
Net loss for the period	(16,902,240)	(6,192,896)
Balance at 30 June	(65,149,999)	(48,247,759)
(b) Reserves		
Net unrealised gains reserve (i)	477,391	832,326
Share-based payments reserve (ii)	2,452,838	2,064,831
Option reserve	1,989,067	1,989,067
Total reserves	4,919,296	4,886,224
(i) Movement in net unrealised gains reserve:		
Opening balance	832,326	_
Unrealised (losses)/gains on available for sale assets	(354,935)	832,326
Closing balance	477,391	832,326
(ii) Movement in share-based payments reserve:		
Opening balance	2,064,831	1,198,971
Share based payments expense	388,007	865,860
Closing balance	2,452,838	2,064,831

#### (c) Nature and purpose of reserves

#### Net unrealised gains reserve

This reserve records fair value changes on listed investments (other than investments in listed associates) and the Group's equity share of its associate's listed investments.

#### Share-based payment reserve

This reserve is used to record the value of equity benefits provided to executives and employees as part of their remuneration and includes the value of options granted to the company's corporate advisors.

#### Option reserve

On 25 November 2014 the company issued options to purchase 49,726,672 ordinary shares with an exercise price of \$0.27 expiring on 25 November 2018. The fair value of the options at their issue date of \$1,989,067 has been recognised in the option reserve.

#### 22. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES

The Group's principal financial assets comprise cash, receivables, short-term deposits and financial investments.

The Group (including the Parent) manages its exposure to key financial risks, including interest rate and currency risk in accordance with the Group's financial risk management practices. The objective is to support the delivery of the Group's financial targets whilst protecting future financial security.

The Group's other various financial assets and liabilities, such as receivables and payables, arise directly from its operations. The main risks arising from the Group's financial assets and liabilities are interest rate risk, foreign currency risk, equity securities price risk and liquidity risk.

The Group uses different methods to measure and manage different types of risks to which it is exposed. These include monitoring levels of exposure to interest rate and foreign exchange risk and assessments of market forecasts for interest rates and foreign exchange rates. Liquidity risk is monitored through future rolling cash flow forecasts.

The board reviews and agrees policies for managing each of these risks as summarised below.

#### Risk exposures and responses

The Group has investigated the main financial risk areas which could impact on its financial assets and determined the impact on post tax (losses) or profits for a range of sensitivities. These can be seen in the post tax (loss)/profit impact for each risk area.

For each risk area, the equity impact relates solely to reserve movements and excludes retained earnings movements as the impact of these can be seen within the post tax (loss)/profit impact.

#### (i) Interest rate risk

The Group's exposure to market interest rates relates primarily to the short-term deposits. The deposits are held with one of Australia's largest banks.

The objective of managing interest rate risk is to minimise the Group's exposure to fluctuations in interest rates that might impact its interest revenue and cash flow. To manage interest rate risk, the Group invests the majority of its cash in short-term deposits for varying periods of between 30 days and 90 days, depending on the short and long-term cash requirements of the Group which is determined based on the Group's cash flow forecast. This consideration also takes into account the costs associated with recalling a term deposit should early access to cash and cash equivalents be required. Cash is not locked into long-term deposits at fixed rates so as to mitigate the risk of earning interest below the current floating rate.

The Group does not have any borrowings.

The following sensitivity analysis (an annual effect) is based on the interest rate risk exposures in existence at 30 June 2018.

As at 30 June 2018, if interest rates moved, with all variables held constant, post tax (loss)/profit and equity would have been affected as illustrated in the following table:

	Post tax profit in	•	Cost of investment	
Judgements of reasonably possible movements	2018 \$	2017 \$	2018 \$	2017 \$
+ 0.50% (50 basis points) (2017: + 0.50%)	103,403	173,403	_	-
- 0.50% (50 basis points) (2017: - 0.50%)	(103,403)	(173,403)	_	_

Given the amount of unrecognised tax losses in existence, the post tax figures include an offset of these tax losses (bringing the tax effect to nil) for the year ended 30 June 2018 (2017: Nil).

#### 22. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (CONT.)

Significant assumptions used in the interest rate sensitivity analysis include:

- / The reasonably possible movement of 0.5% was calculated by taking the interest rates as at balance date, moving these by plus and minus 0.5% and then re-calculating the interest on term deposits with the 'new-interest-rate'.
- / The net exposure at balance date is representative of what the Group was and is expecting to be exposed to in the next twelve months from balance date.

#### (ii) Price risk

The Group's investment in listed shares is exposed to equity securities price risk and as such their fair values are exposed to fluctuations as a result of changes in market prices.

Equity price risk is the risk that the fair value of equities will decrease as a result of share price movements. The Group's equity investments are publicly traded on the ASX and are designated and accounted for as "available-for-sale" financial assets.

The investments in listed shares are not held for short-term trading. Their values are reviewed regularly by management and the board. The strategy for realising any part of these investments is determined based on the liquidity of the respective stocks, potential off-market acquirers and likely developments in their values based on publicly available information.

At 30 June 2018, had the share price moved with all other variables held constant, post tax (loss)/profit and equity would have been affected as illustrated in the table below:

	Impact of loss after tax	Impact on equity after tax	Impact on loss after tax	Impact on equity after tax
Judgements of reasonably possible movements	2018 \$	2018 \$	2017 \$	2017 \$
Change in variables				
10% increase in listed share price	55,531	55,531	80,377	80,377
10% decrease in listed share price	(55,531)	(55,531)	(80,377)	(80,377)

#### (iii) Foreign currency risk

As a result of services provided by non-related entities in the United States, Canada, United Kingdom and Europe, part of the Group's financial assets and liabilities are affected by movements in the exchange rate.

The Group does not enter into any hedging transactions.

At the reporting date, the Group has the following exposure to foreign currencies:

		Consolid	ated	
	USD	EURO	GBP	CAD
2018	2018 \$	2018 \$	2018 \$	2018 \$
Financial assets				
Cash	572,624	_		_
Receivables	110,274	_	_	-
Financial liabilities				
Payables	(1,858,053)	(143,449)	(94,563)	(6,426)
Net exposure	(1,175,155)	(143,449)	(94,563)	(6,426)

#### 22. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (CONT.)

	Consolidated			
2017	USD	EURO	GBP 2017 \$	CAD 2017 \$
	2017 \$	2017 \$		
Financial assets				
Cash	930,586	_	_	-
Receivables	63,529	_	_	-
Financial liabilities				
Payables	(400,509)	(128,466)	(7,572)	(1,202)
Net exposure	593,606	(128,466)	(7,572)	(1,202)

The following sensitivity is based on the foreign currency risk exposures in existence at 30 June 2018.

At 30 June 2018, had the Australian dollar moved with all other variables held constant, post tax (loss) profit and equity would have been affected as illustrated in the table below:

		Post tax (loss)/ profit impact		Cost of investment	
Judgements of reasonably possible movements	2018 \$	2017 \$	2018 \$	2017 \$	
Consolidated					
AUD/USD +10% (2017: +10%)	319,556	(37,775)	_	_	
AUD/USD -10%	(390,568)	46,169	_	_	
AUD/Euro +10% (2017: +10%)	2,421	8,175	_	_	
AUD/Euro –10%	(2,959)	(9,992)	_	_	
AUD/GBP +10% (2017: +10%)	14,773	482	_	_	
AUD/GBP –10%	(18,056)	(589)	_	_	
AUD/CAD +10% (2017: +10%)	461	77	_	_	
AUD/CAD -10%	(564)	(94)	_	_	

The reasonably possible movements at 30 June 2018 are higher than at 30 June 2017 due mainly to the higher net exposure to the US dollar. There was minimum or insignificant exposure to the GBP, Euro and CAD during the current financial year.

Significant assumptions used in the foreign currency exposure sensitivity analysis include:

The reasonably possible movement of 5% was calculated by taking the currency spot rates as at balance date, moving these by 5% and 10% and then re-converting the currencies into AUD with the 'new-spot-rate'. This methodology reflects the translation methodology undertaken by the Group.

The net exposure at balance date is representative of what the Group was and is expecting to be exposed to in the next twelve months from balance date.

Management believes the balance date risk exposures are representative of the risk exposure inherent in the financial instruments.

#### 22. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (CONT.)

#### (iv) Credit risk

Credit risk is associated with those financial assets of the Group which comprise cash and cash equivalents and listed investments. The Group's exposure to credit risk arises from default of the counter party, with a maximum exposure equal to the carrying amount of these investments. Credit risk is considered minimal as the Group transacts with reputable recognised Australian banks.

#### (v) Liquidity risk

Liquidity risk arises from the financial liabilities of the Group and the Group's subsequent ability to meet their obligations to repay their financial liabilities as and when they fall due. The Group has minimal liquidity risk because of the high balances of cash and cash equivalents; however the Group manages liquidity risk by maintaining adequate reserves and by continuously monitoring forecast and actual cash flows and by matching the maturity profiles of financial assets and liabilities.

The Group's objective is to maintain an appropriate cash asset balance to fund its operations.

#### (vi) Fair value

The Group has investments in listed equities which are calculated using the quoted prices in an active market. These investments are classified as falling into level 1 hierarchy per AASB 13 'Fair Value Measurement'. The Group does not have any derivative investments (level 2 hierarchy) where the fair value is estimated using inputs other than quoted prices included in level 1 that are observable for the asset or liability, either directly (as prices) or indirectly (i.e. derived from prices). The Group also does not hold any financial instruments that fall into level 3. Level 3 fair value measurement uses observable inputs that require significant adjustments based on observable inputs to estimate its value.

Details of the fair value of the available-for-sale financial assets are disclosed in note 15 of the financial statements.

The fair value of current assets and liabilities in the consolidated statement of financial position at 30 June 2018 is the same as their carrying amounts.

The methods for estimating fair value are also outlined in the relevant notes to the financial statements.

#### 23. RELATED PARTY DISCLOSURES

#### (a) Subsidiaries

The consolidated financial statements include the financial statements of Opthea Limited and the subsidiary in the following table:

		Parent entity % equity interest		
Name of company	2018 %	2017 %		
Vegenics Pty Ltd <sup>1</sup>	100	100		

<sup>1</sup> Opthea Limited is the ultimate parent entity. Vegenics Pty Ltd is incorporated in Australia and has the same financial year as Opthea Limited. During the year there was a cross guarantee in place in favour of Vegenics Pty Ltd.

#### (b) Transactions with related parties

Balances and transactions between the Company and its subsidiaries, which are related parties of the Company, have been eliminated on consolidation and are not disclosed in this note. Refer to note 28(b) for director related party transactions.

#### 24. CASH FLOW STATEMENT RECONCILIATION

#### (a) Reconciliation to cash at the end of the year

	2018 \$	2017 \$
Cash at bank and in hand (note 13)	32,510,230	51,959,906
	32,510,230	51,959,906
(b) Reconciliation of net loss after tax to net cash flows from operations		
Net loss for the year	(16,902,240)	(6,192,896)
Adjustments for:		
Income tax benefit recognised in profit or loss	(12,017,248)	(3,167,912)
Depreciation of non-current assets	28,655	26,614
Net loss on disposal of non-current assets	513	3,776
Net gain on disposal of subsidiary	-	(2,521)
Share-based payments – directors and employees	388,007	865,860
Net exchange differences	156,433	38,704
	(11,443,640)	(2,235,479)
Movements in working capital:		
(Increase)/decrease in prepayments	(138,300)	28,079
Decrease/(increase) in interest and other receivables	115,234	(287,956)
Increase/(decrease) in payables	5,648,211	(47,181)
Increase in employee provisions	73,420	46,442
Net cash used in operating activities	(22,647,315)	(8,688,991)
Income tax refund	2,709,765	2,643,553
Net cash generated by operating activities	(19,937,550)	(6,045,438)

#### 25. COMMITMENTS

#### (i) Operating lease commitments - Group as lessee

The Group has a commercial lease for its office premises for a period of 6 years from 15 July 2013. The Group also leased laboratory facilities on an annual basis. This ceased in March 2017.

	2018 \$	2017 \$
Within one year	109,442	53,084
After one year but not more than five years	10,963	172,824
	120,405	225,908

#### (ii) Research projects and license commitments

The Group has entered into research and development contracts and intellectual property license agreements with various third parties in respect of services for the Phase 2b wAMD and Phase1b/2a DME clinical trials. Expenditure commitments relating to these and intellectual property license agreements are payable as follows:

	2018 \$	2017 \$
Within one year	24,340,889	1,251,372
After one year but not more than five years	1,982,603	373,411
After more than five years	182,260	201,642
	26,505,752	1,826,425

#### 26. CONTINGENCIES

Opthea and its subsidiary are party to various research agreements with respect to which a commitment to pay is contingent on the achievement of research milestones. Assuming all milestones are achieved within the timeframes stipulated in the contracts, those which could become payable in less than one year total \$NIL (2017: \$NIL) and those which could become payable in more than one year total \$15,834,654 (2017: \$15,313,461). These expenditure commitments would have an offsetting revenue stream from royalties and other income.

Also, under license/collaboration agreements with three third parties, payments are to be made only if certain research and clinical development milestones are achieved and royalties may become payable on any eventual sales of products developed under these agreements.

The group had a bank guarantee outstanding at 30 June 2018 in respect of a rental deposit for its office premises of \$43,841 (2017: \$43,841).

#### 27. KEY MANAGEMENT PERSONNEL

#### (a) Compensation of Key Management Personnel

	2018 \$	2017 \$
Short-term employee benefits	986,755	1,119,155
Post employment benefits	93,742	92,070
Share-based payments expense	196,723	628,861
Total compensation	1,277,220	1,840,086

Details of the key management personnel are included within the Remuneration Report section of the Directors' Report.

#### (b) Other transactions and balances with director and key management personnel and their related parties

There were no director and key management personnel related party transactions during the current or prior financial year.

#### 28. SHARE-BASED PAYMENTS

#### (a) Recognised share based payment expenses

The expense recognised for share-based payments during the year is shown in the table below:

	2018 \$	2017 \$
Expense arising from equity-settled share-based payment transactions:		
Director and employee services received	388,007	865,860

#### (b) Non-executive director and employee share option plans

During the 2015 financial year, the Group introduced an ownership-based compensation scheme for non-executive directors, executives and senior employees, the Long Term Incentive Plan (LTIP) and Non-Executive Directors Share and Option Plan (NED Plan). In accordance with the terms of the plans, as approved by shareholders at the 2014 annual general meeting, eligible non-executive directors, executives and senior employees with the Group may be granted options to purchase ordinary shares.

Each employee share option converts into one ordinary share of Opthea Limited on exercise. No amounts are paid or payable by the recipient on receipt of the option. The options carry neither rights to dividends nor voting rights. Options may be exercised at any time from the date of vesting to the date of their expiry.

The number of options granted is subject to approval by the board and rewards executives and senior employees to the extent of the Group's and the individual's achievement judged against both qualitative and quantitative criteria as determined by the board on a case by case basis.

#### 28. SHARE BASED PAYMENTS (CONT.)

The vesting condition of options granted under the LTIP and NED Plan is continuous service.

Options/Rights series	Grant date	Grant date fair value	Exercise price	Expiry date	Vesting date	
LTIP – director	7 March 2016	\$0.19	\$0.48	7 March 2021	30 June 2016	
LTIP – employees	31 March 2016	\$0.24	\$0.48	1 January 2022	1 January 2017	
LTIP – employees	23 August 2017	\$0.33	\$1.16	1 January 2022	1 January 2017	
NED Plan	7 March 2016	\$0.19	\$0.48	7 March 2021	30 June 2016	

There has been no alteration of the terms and conditions of the above share-based payment arrangements since the grant date.

#### (c) Share-based payment to corporate advisor

In January 2015, the company issued 1,000,000 options to purchase ordinary shares to Bell Potter Securities in consideration for services to be provided under a Corporate Advisory Agreement. The issue of the options was approved by members at the 2014 annual general meeting. The fair value of the options was \$0.075 per option. The options were exercised on 14 December 2017 and converted to 1,000,000 fully paid ordinary shares at an exercise price of \$0.2625.

#### (d) Fair value of share options granted

Where relevant, the expected life used in the model has been adjusted based on management's best estimate for the effects of non-transferability, exercise restrictions (including the probability of meeting market conditions attached to the option), and behavioural considerations. Expected volatility is based on the historical share price volatility over the past 5 years.

	NED Plan	LTIP – Director	LTIP – employees	LTIP – employees FY2018
Grant date share price	\$0.38	\$0.38	\$0.43	\$0.70
Exercise price	\$0.48	\$0.48	\$0.48	\$1.16
Fair value per option	\$0.19	\$0.19	\$0.24	\$0.32
Expected volatility	65%	65%	65%	66%
Option life	5 years	5 years	5 years	5 years
Dividend yield	0%	0%	0%	0%
Risk free interest rate	2.09%	2.09%	2.09%	2.09%
Model used	Binomial	Binomial	Binomial	Binomial

#### 28. SHARE BASED PAYMENTS (CONT.)

#### (e) Movements in share options during the year

The following reconciles the share options outstanding at the beginning and end of the year:

	30 June 2018		30 June 2017	
	Number of options and rights	Weighted average exercise price \$	Number of options and rights	Weighted average exercise price \$
Balance at beginning of year	10,575,000	0.46	10,725,000	0.46
Granted during the year:				
To employees under the LTIP	500,000	1.16	_	_
Exercised during the year	(1,000,000)	0.26	(50,000)	0.48
Expired during the year	-	-	(100,000)	0.48
Balance at end of year	10,075,000	0.51	10,575,000	0.46
Exercisable at end of year	8,847,500	0.49	6,436,250	0.45

The share options outstanding at the end of the year had a weighted average exercise price of \$0.51 (2017: \$0.46) and a weighted average remaining contractual life of 1,091 days (2017: 1,310 days).

#### 29. NET TANGIBLE ASSET BACKING

	2018 \$	2017 \$
Net tangible asset backing per ordinary security	0.19	0.27

#### 30. AUDITORS' REMUNERATION

The auditor of Opthea Limited is Deloitte Touche Tohmatsu.

	2018 \$	2017 \$
Amounts received or due and receivable by Deloitte (Australia) for:		
Audit or review of the financial report of the entity and any other entity in the consolidated group	84,565	84,565
Other services in relation to the consolidated group	4,500	_
	89,065	84,565

#### 31. EVENTS AFTER THE BALANCE SHEET 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.

#### 32. PARENT ENTITY INFORMATION

The accounting policies of the parent entity, which have been applied in determining the financial information shown below, are the same as those applied in the consolidated financial statements. Refer to note 3 for significant accounting policies relating to the Group.

#### (a) Financial position

	2018 \$	2017 \$
Current assets	44,557,305	55,709,767
Non-current assets	862,387	224,764
Total assets	45,419,692	55,934,531
Current liabilities	(7,761,758)	(1,891,304)
Non-current liabilities	(39,396)	(267,817)
Total liabilities	(7,801,155)	(2,159,121)
Net assets	37,618,537	53,775,410
Issued capital	98,403,149	97,853,499
Retained earnings	(65,703,906)	(48,964,312)
Option reserve	1,989,067	1,989,067
Employee equity benefits reserve	2,452,837	2,064,830
Net unrealised gains reserve	477,391	832,326
Total shareholders' equity	37,618,537	53,775,410

#### (b) Financial performance

	Year ended 30 June 2018 \$	Year ended 30 June 2017 \$
Loss of the parent entity	(16,739,594)	(5,878,794)
Other comprehensive (expense)/income	(354,935)	832,326
Total comprehensive loss of the parent entity	(17,094,529)	(5,046,468)

#### (c) Parent entity contractual commitments for acquisition of property, plant and equipment

The parent entity does not have any contractual commitments for the acquisition of property, plant and equipment for the year ended 30 June 2018 (2017: Nil).

#### (d) Parent entity contingent liabilities

The parent entity had a bank guarantee outstanding at 30 June 2018 in respect of a rental deposit for its office premises of \$43,841 (2017: \$43,841).

#### (e) Parent entity guarantees in respect of debts of its subsidiaries

The parent entity has provided a written guarantee to its controlled entity that it will continue to provide sufficient funds to enable it to meet its commitments and contingencies for the next twelve months. The controlled entity is disclosed in note 23.

# DIRECTORS' DECLARATION FOR THE YEAR ENDED 30 JUNE 2018

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 consolidated entity's financial position as at 30 June 2018 and of its performance for the year ended on that date; and
    - (ii) complying with Australian Accounting Standards, Corporations Regulations 2001, and International Financial Reporting Standards (IFRS) as disclosed in note 3 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 295A of the *Corporations Act 2001* for the financial year ended 30 June 2018.

Signed in accordance with a resolution of the directors made pursuant to S.295(5) of the Corporations Act 2001. On behalf of the directors:

Megan Baldwin

CEO & Managing Director Opthea Limited

Melbourne 28 August 2018 **Geoffrey Kempler** 

Chairman Opthea Limited

### INDEPENDENT AUDITOR'S REPORT

### Deloitte.

Deloitte Touche Tohmatsu ABN 74 490 121 060

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

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

#### Report on the Audit of the Financial Report

#### Opinion

We have audited the financial report of Opthea Limited (the "Company") and its subsidiaries (the "consolidated entity"), which comprises the consolidated statement of financial position as at 30 June 2018, the consolidated statement of profit or loss and other comprehensive income, the consolidated statement of cash flows and the consolidated statement of changes in equity for the year then ended, and notes to the financial statements, including a summary of significant accounting policies, and the directors' declaration.

In our opinion the accompanying financial report of Opthea Limited, is in accordance with the *Corporations Act 2001*, including:

- giving a true and fair view of the consolidated entity's financial position as at 30 June 2018 and of its financial performance for the year then ended; and
- (ii) complying with Australian Accounting Standards and the Corporations Regulations 2001.

#### Basis for Opinion

We conducted our audit in accordance with Australian Auditing Standards. Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Financial Report section of our report. We are independent of the consolidated entity in accordance with the auditor independence requirements of the Corporations Act 2001 and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 Code of Ethics for Professional Accountants (the Code) that are relevant to our audit of the financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

We confirm that the independence declaration required by the *Corporations Act 2001*, which has been given to directors of the Company, would be in the same terms if given to the directors as at the time of this auditor's report.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### **Key Audit Matters**

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial report of the current period. These matters were addressed in the context of our audit of the financial report as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

Liability limited by a scheme approved under Professional Standards Legislation.

Member of Deloitte Touche Tohmatsu Limited

#### **Deloitte**

#### **Key Audit Matter**

#### Authorisation and classification of

Opthea Limited operates in the biotechnology market and is in the clinical research stage of developing a molecule asset, OPT-302, for eye diseases, as disclosed in Note 4.1.

The majority of Opthea's expenditure is incurred as a result of clinical trials for OPT-302. In 2018, Opthea diversifed and expanded its clinical development program including the commencement of the following clinical trials:

- Phase 2b clinical trial of OPT-302 in treatment naïve wet AMD patients, and
- Phase 1b/2a clinical trial for diabetic macular edema (DME)

The commencement of these clinical trials resulted in a significant increase in the research expenditure incurred during the 12 month period.

A key measure of Opthea's performance is the level of expenditure incurred on the research of OPT-302. The authorisation and classification of expenses requires judgement as the cash assets of the Group are primarily expended in the research of OPT-302 and therefore there is a risk that:

- Expenses may be incorrectly classified and disclosed, and
- Expenses may not be appropriately approved.

How the scope of our audit responded to the Key Audit Matter

Our procedures included, but were not limited to:

- Obtaining an understanding of the process undertaken by management to account for expenditure, with a particular focus on research expenditure,
- Assessing and testing key controls in respect of the expenditure process,
- Assessing the appropriateness of management's accounting policy for research expenditure,
- Testing on a sample basis, research expenses to evalutate whether they were authorised in accordance with the Group's Delegation of Authority, and
- Assessing documentation for a sample of research expenses to determine whether they were correctly classified.

We also assessed the appropriateness of the disclosures in Note 9 and 10 to the financial statements.

#### Other Information

The directors are responsible for the other information. The other information comprises the information included in the annual report, but does not include the financial report and our auditor's report thereon.

Our opinion on the financial report does not cover the other information and we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial report, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial report or our knowledge obtained in the audit or otherwise appears to be materially misstated.

If, based on the work we have performed, we conclude that there is a material misstatement of this other information; we are required to report that fact. We have nothing to report in this regard.

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

#### Deloitte.

#### Responsibilities of the Directors for the Financial Report

The directors are responsible for the preparation of the 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 financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

In preparing the financial report, the directors are responsible for assessing the consolidated entity's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the consolidated entity or to cease operations, or have no realistic alternative but to do so.

#### Auditor's Responsibilities for the Audit of the Financial Report

Our objectives are to obtain reasonable assurance about whether the financial report as a whole is free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with the Australian Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of this financial report.

As part of an audit in accordance with the Australian Auditing Standards, we exercise professional judgement and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial report, whether
  due to fraud or error, design and perform audit procedures responsive to those risks,
  and obtain audit evidence that is sufficient and appropriate to provide a basis for our
  opinion. The risk of not detecting a material misstatement resulting from fraud is higher
  than for one resulting from error, as fraud may involve collusion, forgery, intentional
  omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit
  procedures that are appropriate in the circumstances, but not for the purpose of
  expressing an opinion on the effectiveness of the consolidated entity's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the directors.
- Conclude on the appropriateness of the directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the consolidated entity's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial report or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the consolidated entity to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the financial report, including
  the disclosures, and whether the financial report represents the underlying transactions
  and events in a manner that achieves fair presentation.

We communicate with the directors regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

#### **Deloitte**

We also provide the directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the directors, we determine those matters that were of most significance in the audit of the financial report of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in our report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

#### **Report on the Remuneration Report**

Opinion on the Remuneration Report

We have audited the Remuneration Report included in pages 13 to 19 of the Directors' Report for the year ended 30 June 2018.

In our opinion, the Remuneration Report of Opthea Limited, for the year ended 30 June 2018, complies with section 300A of the *Corporations Act 2001*.

#### Responsibilities

The directors of Opthea Limited are responsible for the preparation and presentation of the Remuneration Report in accordance with section 300A of the *Corporations Act 2001*. Our responsibility is to express an opinion on the Remuneration Report, based on our audit conducted in accordance with Australian Auditing Standards.

DELOTTE TOUCHE TOHMATSU

DELOITTE TOUCHE TOHMATSU

Samuel Vorwerg

Partner

Chartered Accountants Melbourne, 28 August 2018

### ASX ADDITIONAL INFORMATION

#### 1. DISTRIBUTION OF EQUITY SECURITIES

The number of shareholders, by size of holding, of quoted fully paid ordinary shares as at 8 August 2018 is as follows:

	Fully paid ordinary shares	
Category	No. of holders	No. of shares
1 – 500	109	22,585
501 – 1,000	318	298,435
1,001 – 5,000	1,031	2,713,474
5,001 – 10,000	400	3,072,280
10,001 – 100,000	558	17,842,042
100,001 – 9,999,999	91	178,849,072
Total	2,507	202,797,888
Number of shareholders holding less than a marketable parcel of shares	182	76,167

#### 2. TWENTY LARGEST SHAREHOLDERS

The names of the 20 largest holders of quoted fully paid ordinary shares and their respective holdings at 8 August 2018 are:

Rank	Name	No. of shares	% interest
1	HSBC Custody Nominees (Australia) Limited	55,496,650	27.37
2	Citicorp Nominees Pty Limited	24,573,666	12.12
3	National Nominees Limited	12,608,910	6.22
4	UBS Nominees Pty Ltd	9,892,114	4.88
5	Armada Trading Pty Limited	8,864,824	4.37
6	Jagen Pty Ltd	8,766,246	4.32
7	J P Morgan Nominees Australia Limited	5,229,043	2.58
8	Merrill Lynch (Australia) Nominees Pty Limited	5,112,094	2.52
9	Ludwig Institute For Cancer Research Ltd	3,122,090	1.54
10	Abingworth Bioequities Master Fund Ltd	2,580,647	1.27
11	CS Third Nominees Pty Limited	2,570,053	1.27
12	Brispot Nominees Pty Ltd	2,454,459	1.21
13	Mrs Margaret Lynette Harvey	2,302,000	1.14
14	JI Family Nominees Pty Ltd	2,150,538	1.06
15	LI Family Nominees Pty Ltd	2,150,538	1.06
16	BNP Paribas Nominees Pty Ltd	2,076,414	1.02
17	Megan Baldwin	1,643,223	0.81
18	Montoya Pty Ltd	1,380,928	0.68
19	Capital Macquarie Pty Limited	1,379,170	0.68
20	Sandhurst Trustees Ltd	1,376,713	0.68
	Totals: Top 20 holders of ordinary fully paid shares	155,730,320	76.79
	Total remaining holders balance	47,067,568	23.21

#### 3. SUBSTANTIAL SHAREHOLDERS

The following information is current at 8 August 2018 based on information extracted from the substantial shareholding notices given to the Company by shareholders who hold relevant interests in more than 5 per cent of the Company's voting shares:

Name	No. of shares
BVF Partners LP	32,488,784
Regal Funds Management Pty Ltd	18,936,079
Baker Brothers Life Sciences LP	16,385,959

#### 4. VOTING RIGHTS

Clauses 44 to 53 of the Company's Constitution stipulate the voting rights of members. In summary, but without prejudice to the provisions of the Constitution, every member present in person or by representative, proxy or attorney shall have one vote on a show of hands and on a poll have one vote for each ordinary share held by the member.

The Company's shares are quoted on the Australian Securities Exchange Limited (ASX code: OPT).

### CORPORATE INFORMATION

#### COMPANY

Opthea Limited

ABN 32 006 340 567

#### **DIRECTORS**

Geoffrey Kempler

B.Sc. Grad. Dipp. App. Soc. Psych (Chairman)

Megan Baldwin

PhD MAICD (Managing Director and Chief Executive Officer)

Michael Sistenich

MSc.

#### **COMPANY SECRETARY**

Mike Tonroe

BSc(Hons) ACA MAICD

#### REGISTERED OFFICE

Level 4, 650 Chapel Street, South Yarra, Victoria 3141

#### **Principal Administrative Office**

Level 4, 650 Chapel Street, South Yarra, Victoria 3141

www.opthea.com

Telephone: +61 (3) 9826 0399 Facsimile: +61 (3) 9824 0083

#### **BANKERS**

Commonwealth Bank of Australia

Melbourne, Victoria

#### **AUDITORS**

Deloitte Touche Tohmatsu

550 Bourke Street, Melbourne, Victoria 3000

#### **SOLICITORS**

Gilbert and Tobin

101 Collins Street, Melbourne, Victoria 3000

#### SHARE REGISTER

Computershare Investor Services Pty Ltd

Yarra Falls, 452 Johnston Street, Abbotsford, Victoria 3067

Telephone: +61 (3) 9415 4000 or

1300 850 505 (within Australia)

#### STOCK EXCHANGE LISTING

Opthea Limited's shares are quoted on the Australian Securities Exchange Limited ASX (code: OPT).

