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# TO IMPROVE THE VISION OF MILLIONS



# wet AMD and DME trials





# The leading cause of blindness in people >50 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

#### WHAT IS wet AMD?

Positive data reported for Ph1b DME (Oct'18)

Wet AMD is marked by loss of vision caused by degeneration of the central portion of the retina (the macula). Blood vessels grow abnormally under the retina, resulting in leakage of fluid and protein from the vessel.

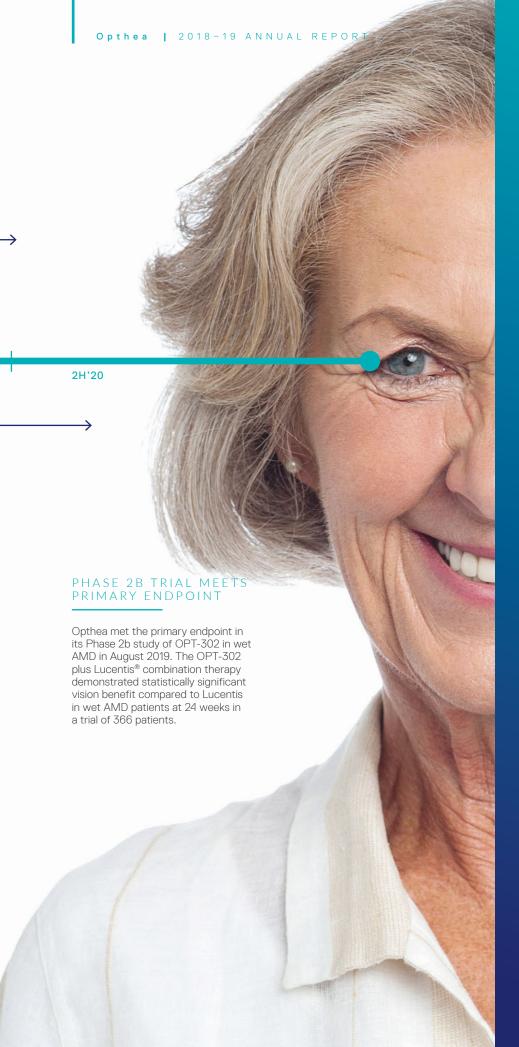
Wet AMD is the leading cause of blindness in the developed world in people aged over 50 years. The disease affects central vision and the ability to see fine detail, such as that required to read, distinguish faces and drive a car. Wet AMD is caused by the abnormal growth and leakage of blood vessels at the back of the eye, which causes degeneration of the retina and vision loss.

The abnormal growth and leakiness of vessels can be stimulated by members of the vascular endothelial growth factor (VEGF) family of proteins, which includes VEGF-A, VEGF-C and VEGF-D.

Elevated levels of these signals and their receptors are associated with retinal disease progression.

Current treatments for wet AMD target VEGF-A. Whilst VEGF-A inhibitors represent a major advance in the management of the disease, many patients respond sub-optimally.

OPT-302 is an inhibitor of VEGF-C and VEGF-D that is being developed as a complementary medicine to be used in conjunction with VEGF-A inhibitors to improve vision outcomes in wet AMD and DME patients.





- 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

#### WHAT IS DME?

Diabetic Macular Edema (DME) is the leading cause of blindness in diabetics. Chronically elevated blood glucose levels in Type 1 and Type 2 diabetics can lead to inflammation, vascular dysfunction and hypoxia, causing upregulation of members of the VEGF family of growth factors, particularly VEGF-A and VEGF-C. Elevated levels of VEGF-A and VEGF-C can lead to fluid accumulation in the macula at the back of the eye and retinal thickening which affects vision.

Existing standard of care treatments for DME are limited and include inhibitors of VEGF-A, steroids and laser therapy. Despite these treatments, many patients remain refractory and have sub-optimal response to therapy with persistent fluid and impaired vision.

OPT-302 blocks the activity of VEGF-C and VEGF-D. Used in combination with a VEGF-A inhibitor, OPT-302 has the potential to improve clinical outcomes in DME patients.

# MESSAGE FROM THE CHAIRMAN AND CHIEF EXECUTIVE

#### DEAR FELLOW SHAREHOLDERS

It is a pleasure to report to our fellow shareholders following a very positive year for Opthea.

Underpinning our progress over the past 12 months was the reporting of outcomes from Opthea's Phase 2b clinical trial in wet AMD patients. This large, international study met the pre-specified primary endpoint of demonstrating significant superior vision gains in patients treated with OPT-302 (2.0 mg) combination therapy compared to standard of care Lucentis® therapy alone.

The positive outcomes of the study represent a major achievement for the company and position Opthea as a global player in ophthalmology.

Importantly, our results highlight the potential of OPT-302 to improve vision outcomes for patients suffering from serious, sight-threatening diseases that affect the back-of-the-eye, including wet age-related macular degeneration (wet AMD) and diabetic macular edema (DME). There are currently limited treatment options for patients with wet AMD and DME, and a large proportion of patients who, despite regular ongoing treatment with existing agents, respond sub-optimally or not at all. OPT-302 offers hope to wet AMD and DME patients that vision outcomes may be better when added to standard of care treatment for these diseases

Our conviction to progress development of OPT-302 is based on multiple factors. Firstly, in addition to the need for new therapies for these diseases, the commercial opportunity for OPT-302 as a combination treatment for use with approved standard of care therapies is currently in excess of USD10 billion per annum and growing. Furthermore, our strategy to target VEGF-C and VEGF-D

for the treatment of retinal eye diseases is based on strong scientific rationale and robust preclinical and clinical data. VEGF-C and VEGF-D are members of the Vascular Endothelial Growth Factor (VEGF) family of signals which are key drivers of vessel growth and vascular permeability, both of which are involved in the pathogenesis of wet AMD and DME. The positive outcomes recently reported from the Phase 2b clinical trial position Opthea well-ahead in the competitive landscape of other companies developing new therapies with novel mechanisms of action for the treatment of wet AMD.

Over the past 12 months we have also made significant progress in diversification of our clinical program into a second eye disease, DME. In October 2018, we reported data from the Phase 1b dose escalation study for OPT-302 in 9 patients with persistent central-involved DME despite prior anti-VEGF-A therapy. Vision and reductions in retinal fluid were observed in patients following addition of OPT-302 to standard of care treatment, with dose responsive gains in visual acuity

The results of the Phase 2b trial of OPT-302 represent a significant step forward for the treatment of patients with retinal vascular diseases, such as wet aged-related macular degeneration (wAMD) and diabetic macular edema (DME).



demonstrated with ascending dose-levels of OPT-302. We are highly encouraged by the outcomes in this trial to date and look forward to reporting data from the larger Phase 2a clinical trial in early 2020.

On the back of strong clinical data, we are now planning to rapidly advance OPT-302 into pivotal, registrational Phase 3 development, and we are in a strong financial position to undertake this planning and complete the DME trial. The company's current cash position is in excess of A\$30 million, which includes A\$12.6 million received through the exercise of quoted options in late 2018 and by the receipt of an A\$14.6 million tax rebate for R&D activities conducted in the 2019 financial year.

We look forward to the next stage of Opthea's corporate growth as we advance OPT-302 through late-stage clinical development and towards commercialisation. The Opthea management team and Board of Directors are truly excited about the potential of OPT-302 to change the treatment paradigm for wet AMD and DME patients. We thank our shareholders for their continued support, many of whom have supported Opthea for many years and through the early stages of OPT-302's clinical development. Finally, we thank our fellow director Michael Sistenich and all of the dedicated and hard-working members of Opthea's management team for their commitment to the program and the company.

**Geoffrey Kempler** Chairman Opthea Limited

J. (-)

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 2019 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) FCA 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 Alterity Therapeutics. Geoffrey brings extensive experience in investment, business development and the biotechnology industry. As a founder of Alterity Therapeutics, he has held both operational roles and been at the forefront of devising and implementing Alterity's strategic and commercialisation plans. Geoffrey brings experience as Chairman of a dual-ASX-NASDAQ listed biotechnology company 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 & risk 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 Chairman of the board of Enlitic Inc. 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.



# 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	Alterity Therapeutics Limited (formerly 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	Options granted under LTIP and NED Plans
Megan Baldwin	987,723	7,000,000
Geoffrey Kempler	900,960	3,500,000
Michael Sistenich	520,178	2,500,000

Number

#### SHARE OPTIONS

As at 30 June 2019 and the date of this report, details of Opthea's unissued ordinary shares and interests under option are as follows:

#### **Unissued ordinary shares**

At 1 July 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, 46,776,951 options (2018: 1,063,518) were exercised.

All quoted options expired during the financial year.

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

During the 2016, 2018 and 2019 financial years the Company granted 18,919,000 options to purchase ordinary shares to directors and employees under the Long Term Incentive (LTIP) and Non-Executive Director Share and Option (NED) Plans.

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
29 November 2018	29 November 2022	Directors under the LTIP and NED plan	\$0.855	6,000,000
3 April 2019	3 April 2023	Employees under the LTIP	\$0.855	2,844,000
				18,919,000

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 2018-19 included 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 clinical data analysis and clinical drug supply 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 sourcing of standard of care anti-VEGF-A agents (eg. Ranibizumab) used in the clinical studies;
- Direct R&D expenditure amounted to \$31,347,891 (2018: \$24,891,534). Including personnel costs and other R&D support costs which are included in administrative costs, total expenditure in R&D amounted to \$33,679,391 (2018: \$27,111,137);
- Opthea received an R&D tax incentive payment during the year of \$12,017,247 (2018: \$2,709,765); and
- The consolidated net loss of the Group for the year was \$20,910,061 after an income tax benefit of \$14,636,973 (2018: loss of \$16,902,240 after an income tax benefit of \$12,017,248).

#### **Financial Position**

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

- Consolidated cash balances as at 30 June 2019 amounted to \$21,534,919 (2018: \$32,510,230);
- Receivables of \$14,932,759 (2018: \$12,410,980) include the Opthea Group's expected refund of R&D tax incentives for the year to June 2019 of \$14,636,973 (2018: \$12,017,248);
- The Group has a net current asset surplus of \$30,376,200 (2018: \$37,349,456); and
- The net tangible asset backing per share as at 30 June 2019 was \$0.12 (2018: \$0.19); Opthea's share price was \$0.67 (2018: \$0.53).

#### **Opthea: Company Overview**

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

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

OPT-302 is a novel therapeutic being developed by Opthea to improve vision in patients with eye diseases that affect the back-of-the-eye or retina. This lead therapeutic candidate is currently being investigated in two large Phase 2 clinical trials to determine if OPT-302 improves visual acuity in patients receiving standard of care therapy for wet AMD and DME. Opthea has made significant advances in the progress of these studies over the past 12 months.

In August 2019, we reported results of the Phase 2b clinical trial in wet AMD demonstrating superior vision gains in patients receiving OPT-302 + ranibizumab (anti-VEGF-A) combination therapy compared to ranibuzumab alone. We anticipate reporting outcomes from the Phase 2a clinical trial in DME in early 2020.

# Wet AMD and DME Represent Large Commercial Opportunities for Novel Therapies

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

Elevated levels of these signals and their receptors are associated with retinal disease progression.

Current treatments for wet AMD and DME share a common mechanism of action by inhibiting VEGF-A. VEGF-A inhibitors approved for the treatment of these diseases include Lucentis (ranibizumab) and Eylea (aflibercept) which together generated revenues in excess of 9 billion USD in 2018. Despite the widespread use and extraordinary commercial success of this class of therapies for retinal disease, many patients respond sub-optimally. As such, there remains a very large commercial opportunity for novel therapies that can address the unmet medical need in patients that experience sub-optimal gains in visual acuity and/or persistent retinal fluid despite regular administration of existing treatments.

## OPT-302: Opthea's Approach to Address the Unmet Medical Need for Patients with Retinal Disease

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

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

With a scarcity of novel combination therapies in development that may offer improved outcomes for retinal disease patients, Opthea's OPT-302 is a promising drug candidate with large commercial potential that has demonstrated improved visual acuity outcomes in patients when administered in combination with a VEGF-A inhibitor in a randomized, controlled, double-masked Phase 2b clinical study. As such, the commercial potential is substantial, as OPT-302 has the potential to be combined with currently available VEGF-A inhibitors or next generation anti-VEGF-A agents.

#### **Operational update**

Over the past 12 months, Opthea has continued to progress its clinical development program investigating OPT-302 as a combination therapy in two distinct retinal diseases:

#### Wet (neovascular) AMD:

Opthea completed dosing of 366 treatment-naïve patients and reported top-line data from the Company's randomised, controlled Phase 2b clinical trial investigating OPT-302 administered in combination with the VEGF-A inhibitor Lucentis compared to Lucentis alone.

#### Persistent, central-involved DME:

Opthea reported outcomes from a Phase 1b dose-escalation study of OPT-302 administered in combination with Eylea and initiated patient recruitment in a  $\sim\!\!108$  patient Phase 2a trial in persistent DME.

Opthea is fully funded through the remaining Phase 2b trial close-out activities and completion of the ongoing Phase 2a study in diabetic macular edema. The strong cash position of the company follows a successful capital raising completed in April 2017, following release of data from the Company's first-in-human Phase 1/2a clinical trial of OPT-302 in wet AMD. At that time Opthea raised \$45m in an oversubscribed fundraising supported by global healthcare institutional investors. In addition, in October 2018, Opthea received a A\$12.0 million research and development (R&D) tax credit from the Australian Taxation Office and proceeds of A\$12.6m through the exercise of quoted options issued in November 2014.

To facilitate the progression of Opthea's clinical development program, Opthea has entered into research and development contracts with various third parties, including a global contract research organization (CRO) to provide services for the conduct of clinical trials. These activities and forecast expenditure in note 25(ii) (page 44) were anticipated and are consistent with use-of-funds disclosures to shareholders in support of the April 2017 fundraising.

#### Phase 2b wet AMD clinical trial

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

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

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

Patient recruitment into the trial was completed in under 12 months and a number of months ahead of projected timelines, reflecting the commitment of both patients and clinical investigators to advance promising new treatments for this debilitating disease. The final patient completed their clinical visit in the Phase 2b study on 15 May 2019 and topline results of the study, reporting that the trial met the primary endpoint, were announced on 7 August 2019.

#### Results of the Phase 2b trial of OPT-302 in Wet AMD

On 7 August 2019 the Company announced positive results from its Phase 2b clinical trial of OPT-302. The prospective, randomized, controlled clinical trial which consisted of 366 treatment-naïve patients with wet AMD, demonstrated that the combination of OPT-302 (2.0 mg) with Lucentis®, met the pre-specified primary endpoint of superiority in mean visual acuity gain at 24 weeks compared to Lucentis monotherapy.

Patients receiving the combination of OPT-302 (2.0 mg) and Lucentis gained a mean of 14.2 letters of vision on the Early Treatment of Diabetic Retinopathy Study (ETDRS) standardized eye chart at 24 weeks, compared to 10.8 letters for patients receiving Lucentis monotherapy, an improvement of 3.4 letters (p=0.0107). Low dose OPT-302 (0.5 mg) combined with Lucentis had similar effects to Lucentis monotherapy (mean visual acuity gain of 9.4 letters at 24 weeks). In addition, OPT-302 (2.0 mg) combination therapy showed improvements across multiple secondary endpoints of functional measures in support of the primary outcome, including a higher proportion of patients with stable vision (defined as  $\leq$  15 letter loss) and also for those gaining  $\geq$ 10 and  $\geq$ 15 letters of visual acuity, compared to Lucentis.

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

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

Retinal thickness was normalized consistently across all treatment groups by week 24. In the OPT-302 (2.0 mg) combination arm, mean CST was reduced from 414  $\mu m$  at baseline to 266  $\mu m$  at week 24, a reduction of 147  $\mu m$ . Similarly, mean CST was reduced by a mean of 134  $\mu m$  to 278  $\mu m$  from baseline to week 24 following Lucentis monotherapy.

#### Phase 1b/2a DME clinical trial

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

The primary safety objective of the Phase 1b dose escalation study of OPT-302 administered in combination with Eylea via sequential intravitreal injection on a monthly basis for three months was met in July 2018. This marked a considerable safety milestone for OPT-302, with a favourable safety profile having been demonstrated in combination with two standard of care anti-VEGF-A therapies, Lucentis (in wet AMD) and Eylea (in DME).

Subsequently, in October 2018 Opthea reported positive three-month data from the 9 patients enrolled in the Phase 1b dose escalation study. Vision improvement and reductions in retinal swelling were observed following conversion to OPT-302 combination treatment in this group of patients with persistent DME, with a clear dose-response relationship of gains in visual acuity with ascending OPT-302 dose levels.

Recruitment into the Phase 2a randomized, controlled dose expansion trial is progressing, with clinical trial sites in the US, Australia, Israel and Latvia. Target enrolment for this trial is ~108 patients, with treatment allocated in a 2:1 ratio to either OPT-302 (2 mg) with Eylea (2 mg) or Eylea (2 mg) monotherapy.

The primary objectives of the Phase 2a study are to evaluate the (i) safety/tolerability and (ii) efficacy of OPT-302 by determination of clinical response rate, defined as the proportion of patients receiving combination OPT-302 and Eylea achieving a  $\geq 5$  letter gain in visual acuity (VA) at week 12 compared to baseline. Secondary outcome measures including evaluation of changes in mean VA and anatomical parameters such as central subfield thickness (CST) and retinal swelling will also be investigated.

Opthea currently anticipates reporting results from the DME trial early in 2020, subject to ongoing patient recruitment.

#### Intellectual property and investor relations

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

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

Over the past 12 months, Opthea has continued to raise the profile of the company's technology to both the international and local investment community. The Company regularly presents and meets with global institutional and retail investors through investor meetings and forums. In November 2018, Opthea hosted a symposium in New York in which internationally recognized key opinion leaders in ophthalmology presented an update on the company's clinical development program and next generation treatments for wet AMD and DME. In addition, Opthea attended the 37th Annual J.P. Morgan Conference in San Francisco in January 2019. The conference attracts investors as well as pharmaceutical and biotechnology executives from around the world and is one of the industry's largest healthcare investment conferences.

Several presentations were also made to the clinical ophthalmology community, with Opthea being invited to present at the Ophthalmology Innovation Summit (OIS) associated with the American Academy of Opthalmology meeting in Chicago. An update on Opthea's wet AMD and DME clinical trial results was also made recently in February 2019 at the Bascom Palmer Angiogenesis meeting in Miami and at the Ophthalmology Innovation Summit at the American Society Retinal Specialists (OIS@ASRS) meeting in July 2019. Further data presentations, including detailed presentations on the Company's Phase 2b clinical trial results are planned over the next 12 months.

# 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 advance the clinical development of OPT-302 to key commercial milestones by progressing patient recruitment into the company's Phase 2a clinical trial with OPT-302 in persistent DME patients, as well as trial close-out activities for the Phase 2b wet AMD study. The reporting of primary data analysis from the DME trial is currently anticipated early in 2020, subject to ongoing patient recruitment.

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

#### wet AMD:

- Prepare and complete the Phase 2b wet AMD clinical study report;
- Publish outcomes of the Phase 2b wet AMD trial in a peer reviewed journal; and
- / Develop plans to take OPT-302 for the treatment of wet AMD to the next stage of its clinical development.

#### Phase 2a DME trial:

- Complete patient enrolment in the US, Australia, Israel and Latvia for the Phase 2a clinical trial in DME patients;
- Complete the 3-month dosing regimen in patients enrolled in the Phase 2a DME clinical trial and complete close-out activities for the trial to facilitate primary data analysis and reporting of outcomes; and
- / Report primary data analysis of the Phase 2a clinical trial in early 2020.

#### Corporate:

- / Ensure the global investment and pharmaceutical/ biotechnology community is aware of the commercial potential inherent in OPT-302; and
- With the goal of optimising shareholder value, prepare for and strategically place Opthea for various and all opportunities to advance further development of OPT-302 through investment out-reach and engagement with pharmaceutical/biotechnology companies in the sector.

# SIGNIFICANT EVENTS AFTER BALANCE DATE

The Company released the initial results of the Phase 2b clinical trial of OPT-302 in wet AMD patients on 7 August 2019. Except for this event there were no significant events after 30 June 2019 to report.

#### **ENVIRONMENTAL REGULATIONS**

The Company is not subject to significant environmental regulations.

#### INDEMNIFICATION AND INSURANCE

During the financial year ended 30 June 2019, 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 2019. 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' 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: 7	4	5	
Number of meetings attended:			
Geoffrey Kempler 7	4	5	
Michael Sistenich 7	4	5	
Megan Baldwin 7	4	5	

#### 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 17 and forms part of the directors' report for the financial year ended 30 June 2019.

# 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.

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

#### **Principles of compensation**

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

#### **Diversity**

The directors consider annually if the diversity of the Company's personnel is appropriate. During the two years ended 30 June 2019, a third of the directors and 56% of employees were female.

#### **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 KPIs, 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 2019 financial year in July 2019. Based on the achievement of operational objectives in the financial year, the remuneration committee has determined there will be \$189,091 STI bonus paid to KMP for the 2019 financial year (2018: \$240,775).

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.

#### Consequences of performance on shareholder wealth

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

	2019 \$	2018 \$	2017 \$	2016 \$	2015 \$
Revenue	914,840	1,143,822	573,421	765,274	939,008
Loss before tax	(35,547,034)	(28,919,488)	(9,360,808)	(8,100,978)	(8,121,254)
Tax benefit	14,636,973	12,017,248	3,167,912	1,569,204	2,720,260
Loss after tax	(20,910,061)	(16,902,240)	(6,192,896)	(6,531,774)	(5,400,994)
	2019 \$	2018 \$	2017 \$	2016 \$	2015 \$
Basic loss per share	(0.09)	(0.08)	(0.04)	(0.04)	(0.05)
NTA backing per share @ 30 June	0.12	0.19	0.27	0.10	0.15
Opthea share price @ 30 June	0.67	0.53	0.75	0.50	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 \$440,000 per annum from 1 November 2018.
- 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. Approval of further grant of options to non-executive directors under the NED Plan was made at the 2018 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' 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	Term- ination benefits	Share- based payment		Total
		Salary & Fees \$	Cash bonus <sup>1</sup> \$	Super- annuation \$	Long Service Leave \$	Term- ination Pay \$	Options \$	Total	perform- ance related %
Non-Executive d	irectors	3:							
Geoffrey Kempler	2019	90,405	_	8,589	_	-	175,798	274,792	64%
	2018	90,405	_	8,589	_	-	44,267	143,261	31%
Michael Sistenich	2019	60,000	_	5,700	_	-	175,798	241,498	73%
	2018	60,000	-	5,700	_	-	22,133	87,833	25%
Sub-total									
Non-executive	2019	150,405	_	14,289	_	-	351,596	516,290	68%
directors	2018	150,405	-	14,289	_	-	66,400	231,094	29%
Executive director	ors:								
Megan Baldwin	2019	413,500	126,750	51,324	_	_	351,597	943,171	51%
	2018	360,500	180,250	51,371	_	_	88,533	680,654	39%
Other Key Manag	gement	Personnel:							
Mike Tonroe	2019	249,363	62,341	29,612	_	-	49,113	390,429	29%
	2018	242,100	60,525	28,749	_	_	41,790	373,164	27%
Totals	2019	813,268	189,091	95,225	_	_	752,306	1,849,890	51%
	2018	753,005	240,775	94,409	_	_	196,723	1,284,912	34%

<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	3,000,000	29 November 2018	0.20	0.855	29 November 2022	-		
Geoffrey Kempler	1,500,000	29 November 2018	0.20	0.855	29 November 2022	-		
Michael Sistenich	1,500,000	29 November 2018	0.20	0.855	29 November 2022	-		
Mike Tonroe	600,000	3 April 2019	0.26	0.855	3 April 2023	272,000 <sup>1</sup>		

<sup>1</sup> Options that vested during the financial year were originally granted on 31 March 2016.

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 to KMP on the exercise of options previously granted as compensation.

#### 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>	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	
	3,000,000	29 November 2018	0%	0%	1 July 2019	
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	
	1,500,000	29 November 2018	0%	0%	1 July 2019	
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	
	1,500,000	29 November 2018	0%	0%	1 July 2019	
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	100%	0%	1 July 2018	
	600,000	3 April 2019	0%	0%	1 July 2019	

Financial

<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

During the reporting period, 6,600,000 options over ordinary shares in the Company were granted to KMP.

#### **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		Held at	Granted as compen-	Options		- 4 15 1	Held at	Vested during	Vested and
of options:		1 July	sation	exercised	Lapsed	Forfeited	30 June	the year	exercisable
Megan Baldwin	2019	4,000,000	3,000,000	_	_	_	7,000,000	-	4,000,000
	2018	4,000,000	_	_	_	-	4,000,000	1,360,000	4,000,000
Geoffrey Kempler	2019	2,000,000	1,500,000	-	-	-	3,500,000	-	2,000,000
	2018	2,000,000	-	-	_	-	2,000,000	680,000	2,000,000
Michael Sistenich	2019	1,000,000	1,500,000	-	-	-	2,500,000	-	1,000,000
	2018	1,000,000	-	_	-	-	1,000,000	340,000	1,000,000
Other executives	;								
Mike Tonroe	2019	800,000	600,000	-	-	-	1,400,000	272,000	800,000
	2018	800,000	-	-	-	-	800,000	264,000	528,000
Total	2019	7,800,000	6,600,000	_	_	-	14,400,000	272,000	7,800,000
	2018	7,800,000	_	_	_	_	7,800,000	2,644,000	7,528,000

#### 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 remuneration	On Exercise of Quoted Options	Purchased in the year	Sold during the year	Balance at end of period 30 June
Non-executive directors							
Geoffrey Kempler	2019	615,246	_	285,714	_	_	900,960
	2018	615,246	_	_	_	-	615,246
Michael Sistenich	2019	520,178	-	_	_	_	520,178
	2018	520,178	_	_	_	_	520,178
Executives							
Megan Baldwin	2019	1,643,223	_	11,500	_	(667,000)	987,723
	2018	1,643,223	_	_	_	_	1,643,223
Mike Tonroe	2019	_	_	_	_	_	_
	2018	_	_	_	_	_	_
Total	2019	2,778,647	_	297,214	_	(667,000)	2,408,861
	2018	2,778,647	_	_	_	_	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 9 August 2019.

For and on behalf of the board:

Megan Baldwin

CEO & Managing Director Opthea Limited

Melbourne 9 August 2019

# 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

9 August 2019

Dear Board Members

#### **Opthea Limited**

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

As lead audit partner for the audit of the financial statements of Opthea Limited for the financial year ended 30 June 2019, 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

DELOITTE 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 was appointed CEO and Managing Director of Opthea in February 2014.

Dr Baldwin has 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 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 the University of Melbourne, having Ludwig Institute for Cancer Research. Dr Baldwin is on the board of Ausbiotech and is a member of the Australian Institute of Company Directors.

#### MIKE TONROE BSC(HONS), FCA, 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 Head of Chemistry, Manufacturing & Controls 2008 with responsibilities encompassing research and cGMP manufacturing activities. Mike has over 30 years' industry, working with numerous Contract Manufacturing Organisations overseas and locally in all facets of translational CMC from concept through to Phase 2 studies. In this time, he has successfully guided the manufacture of six biologics through to the clinic, including oversight of four nonclinical programs, as well as associated as Chief Operating Officer of Q-Gen, the manufacturing facility of the Queensland strategic objectives. Mike has also directed the development of numerous in vitro diagnostic products through to the market over 19 years at Agen Biomedical, ultimately as Research and Product his PhD in biotechnology from the 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 since September 2011. He has over 20 years of research and management experience from drug discovery through clinical development in biotechnology/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 Phase 1 – 2 clinical studies in oncology.

Prior to joining Amgen, he spent eight years at Miravant Medical Technologies in Santa Barbara, California. He held positions of increasing responsibility, including Senior Program Manager for Cardiovascular Research and Clinical Study Director for Ophthalmology. At Miravant, he managed preclinical 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 BSc (Hons), PhD from the Department of Pharmacology, Faculty of Medicine, at Monash University and completed part of the doctoral studies at the University of California. Santa Barbara.

#### CLARE PRICE BPHARM

Director of Clinical Development

Clare Price was appointed Director of Clinical Development at Opthea in July 2016. Clare has over 20 years of clinical and drug development experience starting her career in the main R&D function of SmithKline Beecham in the UK.

She spent over eight 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

Clare has held senior clinical roles in two ASX-listed biotechnology companies, firstly Acrux, and then Starpharma. Over her nine years at Starpharma she implemented and delivered successful Phase 2 and 3 clinical programmes, including extensive regulatory interaction and negotiation, leading 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 CRO industries.

Prior to joining Opthea Annette held senior 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 studies in a Phase 1 unit at Nucleus Network and managing European clinical projects while living in the UK and working for Mitsubishi Tanabe Pharma Europe.

Information Management from La Trobe University.



# FINANCIAL REPORT

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# CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE YEAR ENDED 30 JUNE 2019

	Note	2019 \$	2018 \$
Finance revenue		755,776	1,001,509
Other revenue		159,064	142,313
Revenue	7	914,840	1,143,822
Other income	8	81,045	2,766
Research and development expenses	9	(31,347,891)	(24,891,534)
Patent expenses		(161,148)	(160,836)
Intellectual property costs		(112,795)	(97,466)
Administrative expenses	10	(5,174,755)	(4,655,305)
Occupancy expenses	10	(108,904)	(104,502)
Net foreign exchange gain/(loss)		362,574	(156,433)
Loss before income tax		(35,547,034)	(28,919,488)
Income tax benefit	11	14,636,973	12,017,248
Loss for the year		(20,910,061)	(16,902,240)
Other comprehensive income			
Items that may be reclassified subsequently to profit or loss:			
Unrealised gains/(losses) on investments in financial assets		259,864	(354,935)
Other comprehensive income/(loss) for the period, net of tax		259,864	(354,935)
Total comprehensive loss for the year		(20,650,197)	(17,257,175)
Loss for the year is attributable to:			
Non-controlling interests		_	-
Owners of the parent	21	(20,910,061)	(16,902,240)
		(20,910,061)	(16,902,240)
Total comprehensive loss for the year is attributable to:			
Non-controlling interests		-	-
Owners of the parent		(20,650,197)	(17,257,175)
		(20,650,197)	(17,257,175)
Earnings per share for loss attributable to the ordinary equity holders of the parent:			
Basic and diluted loss per share (cents)	12	(8.98)	(8.38)

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 2019

	Note	2019 \$	2018 \$
Assets			
Current assets			
Cash and cash equivalents	13	21,534,919	32,510,230
Current tax receivable	11	14,636,973	12,017,248
Receivables	14	295,786	393,732
Prepayments		424,603	292,257
Total current assets		36,892,281	45,213,467
Non-current assets			
Investments in financial assets	15	714,118	793,301
Plant and equipment	16	54,063	69,086
Total non-current assets		768,181	862,387
Total assets		37,660,462	46,075,854
Liabilities			
Current liabilities			
Payables	17	5,951,942	7,275,505
Provisions	18	538,547	459,432
Other financial liabilities		25,592	129,074
Total current liabilities		6,516,081	7,864,011
Non-current liabilities			
Provisions	19	24,844	38,462
Other liabilities		_	935
Total non-current liabilities		24,844	39,397
Total liabilities		6,540,925	7,903,408
Net assets		31,119,537	38,172,446
Equity			
Contributed equity	20	113,021,993	98,403,149
Accumulated losses	21	(86,060,060)	(65,149,999)
Reserves	21	4,157,604	4,919,296
Total equity		31,119,537	38,172,446

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 2019

	Note	Contrib- uted equity \$	Options reserve	Share- based payments reserve \$	Unrealised gains reserve \$	Accum- ulated losses \$	Total equity \$
As at 1 July 2017		97,853,499	1,989,067	2,064,831	832,326	(48,247,759)	54,491,964
Unrealised loss on investments in financial 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
As at 1 July 2018		98,403,149	1,989,067	2,452,838	477,391	(65,149,999)	38,172,446
Unrealised gains on investments in financial assets*	21	-	-	_	259,864	_	259,864
Loss for the year*		_	_	_	_	(20,910,061)	(20,910,061)
Total comprehensive income and expense for the period		98,403,149	1,989,067	2,452,838	737,255	(86,060,060)	17,522,249
Recognition of share-based payment	21	_	_	967,511	_	-	967,511
Issue of ordinary shares and exercise of quoted options	20	14,618,844	(1,989,067)	-	-	-	12,629,777
Balance at 30 June 2019		113,021,993	_	3,420,349	737,255	(86,060,060)	31,119,537

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

The above consolidated 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 2019

	Note	2019 \$	2018 \$
Cash flows from operating activities		Ť	<u> </u>
Interest received		817,314	774,606
Royalty and licence income received		248,495	157,475
Payments to suppliers, employees and for research & development and intellectual property costs (inclusive of GST)		(37,268,212)	(23,579,396)
Income tax refund		12,017,247	2,709,765
Net cash flows used in operating activities	24	(24,185,156)	(19,937,550)
Cash flows from investing activities			
Cash received on disposal of financial asset		339,046	-
Purchase of plant and equipment		(18,070)	(34,417)
Net cash flows provided by/(used in) investing activities		320,976	(34,417)
Cash flows from financing activities			
Cash received for ordinary shares issued on exercise of options		12,629,777	549,650
Net cash flows provided by financing activities		12,629,777	549,650
Net increase/(decrease) in cash and cash equivalents		(11,234,403)	(19,422,317)
Effects of exchange rate changes on the balance of cash held in foreign currencies		259,092	(27,359)
Cash and cash equivalents at beginning of year		32,510,230	51,959,906
Cash and cash equivalents at the end of the year	13	21,534,919	32,510,230

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 9 August 2019.

# 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 financial assets, 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. The Group has applied the simplified approach under AASB 9 when calculating an expected credit loss. An expected credit loss 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 investments in financial assets, in accordance with AASB 9 Financial Instruments and related amending Standards. AASB 9 is effective for an annual period that begins on or after 1 January 2018. The Group has applied AASB 9 for the first time in the current year. The equity investments are held for long-term strategic purposes and the Group has elected to designate them as fair value through other comprehensive income (FVOCI).

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

When financial assets are recognised initially, they are measured at fair value, plus 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

Investments in financial assets comprise of the Group's noncurrent investments in listed companies. After initial recognition, investments in financial assets are measured at fair value with gains or losses being recognised as a separate component of equity. The fair values of investments in financial assets 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.

#### 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.

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

AASB 16 Leases 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.

AASB 16 is effective for annual periods beginning on or after 1 January 2019. The Group will apply AASB 16 initially on 1 July 2019. The Group has assessed the potential impact on its consolidated financial statements. The amounts disclosed in the accounts would not be materially different if AASB 16 were applied in the 2019 financial year.

The most significant impact identified is that the Group will recognise new assets and liabilities for its lease of office facilities. AASB 16 replaces the straight-line operating lease expense with a depreciation charge for right-of-use assets and interest expense on lease liabilities.

The Group will apply AASB 16 using a modified retrospective approach with optional practical expedients.

#### 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.

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.

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.

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONT.)

#### 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 2019 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.

#### **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 investments in financial assets 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 Accounting Standards 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 9 Financial Instruments and related amending Standards;
- AASB 15 Revenue from Contracts with Customers and related amending Standards;
- AASB 2016-5 Amendments to Australian Accounting Standards – Classification and Measurement of Share-based Payment Transactions;
- AASB 2017-1 Amendments to Australian Accounting Standards
   Transfers of Investment Property, Annual Improvements
   2014-2016 Cycle and Other Amendments; and
- Interpretation 22 Foreign Currency Transactions and Advance Consideration.

### AASB 9 Financial Instruments and related amending Standards

In the current year, the Group has applied AASB 9 Financial Instruments (as amended) and the related consequential amendments to other Accounting Standards that are effective for an annual period that begins on or after 1 January 2018. The transition provisions of AASB 9 allow an entity not to restate comparatives. However, the Group has elected to restate comparatives in respect of the classification and measurement of financial instruments.

Additionally, the Group adopted consequential amendments to AASB 7 Financial Instruments: Disclosures that were applied to the disclosures about the financial year ended 30 June 2019 and to the comparative period.

AASB 9 introduced new requirements for:

- The classification and measurement of financial assets and financial liabilities;
- / Impairment of financial assets; and
- / General hedge accounting.

AASB 9 requires an expected credit loss model as opposed to an incurred credit loss model under AASB 139. The expected credit loss model requires the Group to account for expected credit losses and changes in those expected credit losses at each reporting date to reflect changes in credit risk since initial recognition of the financial assets. The Group has applied the simplified approach when calculating the expected credit loss as part of its accounting policy which has not materially impacted the accounts.

All recognised financial assets that are within the scope of AASB 9 are required to be subsequently measured at amortised cost or fair value on the basis of the entity's business model for managing the financial assets and the contractual cash flow characteristics of the financial assets. Specifically, all equity investments are subsequently measured at fair value through profit or loss.

The Group may irrevocably elect to present subsequent changes in fair value of an equity investment that is neither held for trading nor contingent consideration recognised by an acquirer in a business combination in other comprehensive income (FVTOCI).

For an equity investment designated as measured at FVTOCI, the cumulative gain or loss previously recognised in other comprehensive income is not subsequently reclassified to profit or loss.

The directors of the Company reviewed and assessed the Group's existing financial assets as at 1 July 2018 based on the facts and circumstances that existed at that date.

The Group's investments in equity instruments (neither held for trading nor a contingent consideration arising from a business combination) that were previously classified as available-for-sale financial assets and were measured at fair value at each reporting date under AASB 139 have been designated as at FVTOCI. The change in fair value on these equity instruments continues to be accumulated in the investment revaluation reserve.

### AASB 15 Revenue from Contracts with Customers and related amending Standards

In the current year, the Group has applied AASB 15 Revenue from Contracts with Customers (as amended) which is effective for an annual period that begins on or after 1 January 2018. AASB 15 introduced a 5-step approach to revenue recognition.

The Group's accounting policies for its revenue are disclosed in detail in note 3 above. The application of AASB 15 has not had a significant impact on the financial position and/or financial performance of the Group.

The Group earned royalties and licence fees of \$159,064 (2018: \$142,313) from its intellectual property portfolio during the year. The amount disclosed in the accounts has not been materially affected by applying AASB 15 in the 2019 financial year.

### Other pronouncements adopted for the first time in the current year

In the current year, the Group has applied a number of amendments to Australian Accounting Standards and Interpretations issued by the Australian Accounting Standards Board (AASB) that are effective for an annual period that begins on or after 1 January 2018. Their adoption has not had any material impact on the disclosures or on the amounts reported in these financial statements.

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

At the date of authorisation of the financial statements, the Group has not applied the following new and revised Australian Accounting Standards, Interpretations and amendments that have been issued but are not yet effective:

Standard/amendment	Effective for annual reporting periods beginning on or after
AASB 16 Leases	1 January 2019
AASB 17 Insurance Contracts	1 January 2021
AASB 2014-10 Amendments to Australian Accounting Standards – Sale or Contribution of Assets between an Investor and its Associate or Joint Venture (AASB 10 & AASB 128), AASB 2015-10 Amendments to Australian Accounting Standards – Effective Date of Amendments to AASB 10 and AASB 128 and AASB 2017-5 Amendments to Australian Accounting Standards – Effective Date of Amendments to AASB 10 and AASB 128 and Editorial Corrections	1 January 2022 (Editorial corrections in AASB 2017-5 apply from 1 January 2018)
AASB 2017-6 Amendments to Australian Accounting Standards – Prepayment Features with Negative Compensation	1 January 2019
AASB 2017-7 Amendments to Australian Accounting Standards – Long-term Interests in Associates and Joint Ventures	1 January 2019
AASB 2018-1 Amendments to Australian Accounting Standards – Annual Improvements 2015-2017 Cycle	1 January 2019
AASB 2018-2 Amendments to Australian Accounting Standards – Plan Amendment, Curtailment or Settlement	1 January 2019
AASB 2018-3 Amendments to Australian Accounting Standards – Reduced Disclosure Requirements	1 January 2019
AASB 2018-6 Amendments to Australian Accounting Standards – Definition of a Business	1 January 2020
AASB 2018-7 Amendments to Australian Accounting Standards – Definition of Material	1 January 2020
AASB 2019-1 Amendments to Australian Accounting Standards – References to the Conceptual Framework	1 January 2020
Interpretation 23 Uncertainty over Income Tax Treatments	1 January 2019

#### **AASB 16 Leases**

AASB 16 provides a comprehensive model for the identification of lease arrangements and their treatment in the financial statements for both lessors and lessees. AASB 16 will supersede the current lease guidance including AASB 117 Leases and the related Interpretations when it becomes effective for accounting periods beginning on or after 1 January 2019. The date of initial application of AASB 16 for the Group will be 1 July 2019.

AASB 16 will change how the Group accounts for leases previously classified as operating leases under AASB 117, which were off-balance sheet. On initial application of AASB 16, for all leases (except as noted below), the Group will:

- / Recognise right-of-use assets and lease liabilities in the consolidated statement of financial position, initially measured at the present value of the future lease payments;
- / Recognise depreciation of right-of-use assets and interest on lease liabilities in the consolidated statement of profit or loss; and
- / Separate the total amount of cash paid into a principal portion (presented within financing activities) and interest (presented within operating activities) in the consolidated cash flow statement.

Lease incentives (e.g. rent-free period) will be recognised as part of the measurement of the right-of-use assets and lease liabilities whereas under AASB 117 they resulted in the recognition of a lease liability incentive, amortised as a reduction of rental expenses on a straight-line basis. Under AASB 16, right-of-use assets will be tested for impairment in accordance with AASB 136 Impairment of Assets. This will replace the previous requirement to recognise a provision for onerous lease contracts.

For short-term leases (lease term of 12 months or less) and leases of low-value assets (such as office equipment), the Group has elected to apply the recognition exemption as permitted by AASB 16. The lease payments associated with those leases will be recognised as an expense on a straight-line basis over the lease term.

The preliminary assessment, following the renewal of the leased office premises on 15 July 2019 indicates that the Group will recognise a right-of-use asset of \$452,923 and a corresponding lease liability of \$452,923 in respect of this lease. The impact on profit or loss is to decrease occupancy expenses by \$151,763 and to increase depreciation by \$151,763.

Under AASB 117, all lease payments on operating leases are presented as part of cash flows from operating activities. The impact of the changes under AASB 16 would be to reduce the cash generated by operating activities by \$151,763 and to increase net cash used in financing activities by the same amount.

#### 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 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

	2019 \$	2018 \$
(a) Finance revenue		
Interest from:		
- Bank	750,167	1,001,509
- Other unrelated persons	5,609	_
	755,776	1,001,509
(b) Other revenue		
Royalties and licence fees	159,064	142,313
Total revenue	914,840	1,143,822

#### 8. OTHER INCOME

	2019 \$	2018 \$
Grant income	77,745	_
Other	3,300	2,766
Total other income	81,045	2,766

#### 9. RESEARCH AND DEVELOPMENT EXPENSES

	2019 \$	2018 \$
Research project costs <sup>1</sup>	31,347,891	24,891,534
Total research and development expenses	31,347,891	24,891,534

<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

	2019 \$	2018 \$
(a) Administrative expenses		
Employee benefits expenses:		
Salaries and fees	2,020,795	1,925,671
Cash bonuses	414,423	372,284
Superannuation	217,592	204,927
Share-based payments expense	967,511	388,007
Total employee benefits expense	3,620,321	2,890,889
Other expenses:		
Insurance	377,181	270,491
Investor relations costs	411,181	353,287
Audit and accounting	138,156	168,222
Travel expenses	84,103	69,528
Payroll tax	87,247	88,502
Legal fees	22,464	40,116
Consultancy fees	_	29,784
Other expenses	401,009	715,318
Total other expenses	1,521,341	1,735,248
Depreciation of:		
Equipment and furniture	19,898	15,461
Leasehold improvements	13,195	13,194
Total depreciation expense	33,093	28,655
Loss on disposal of non-current assets	-	513
Total administrative expenses	5,174,755	4,655,305
(b) Occupancy expenses		
Operating lease rentals	78,883	78,199
Outgoings	30,021	26,303
Total occupancy expense	108,904	104,502

#### 11. INCOME TAX

	2019 \$	2018 \$
(a) Income tax benefit		
The major components of income tax benefit are:		
Statement of Comprehensive Income		
Current tax		
Current income tax credit	14,636,973	11,793,345
Under recognition of prior year benefit <sup>1</sup>	_	223,903
	14,636,973	12,017,248
Deferred tax		
In respect of the current year	_	-
Total income tax benefit recognised in the Statement of Comprehensive Income	14,636,973	12,017,248
1 Relates to under recognition of R&D Tax incentive for the 2017 financial year.		
(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	_	-
Income tax benefit reported in equity	-	_
(c) Current tax receivable		
Research and Development Tax Incentive Credit receivable	14,636,973	12,017,248

### (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:

	2019 \$	2018 \$
Accounting loss before tax	(35,547,034)	(28,919,488)
At the parent entity's statutory income tax rate of 27.5%	9,775,434	7,952,859
Research and development tax credit refundable	14,636,973	11,793,345
Write off of temporary differences and tax losses not recovered	(9,775,434)	(7,505,053)
Adjustments recognised in current year in relation to the current tax of prior year	-	(223,903)
Income tax benefit reported in the statement of comprehensive income	14,636,973	12,017,248

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

	2019 \$	2018 \$
(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)	(56,114)	(95,043)
	(56,114)	(95,043)
Deferred tax assets:		
Other timing differences including income received in advance	151,821	230,803
Employee provisions	154,933	149,368
Temporary differences:		
Associated with other miscellaneous items	276,942	540,840
	583,696	921,011
Less: temporary differences not recognised	(527,582)	(825,968)
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 \$527,582 at year end (2018: \$825,968).

#### (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 \$15,819,190 and capital losses of \$877,704 at year end (2018: income tax losses of \$15,196,881 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 (2018: \$330,630), which represents the amount of franking credits available for the subsequent financial year.

#### 12. EARNINGS PER SHARE

	2019 \$	2018 \$
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	(20,910,061)	(16,902,240)
(b) Weighted average number of shares		
Weighted average number of ordinary shares on issue for basic earnings per share	232,795,371	201,580,604
Effect of dilution:		
Share options	_	_
Weighted average number of ordinary shares adjusted for the effect of dilution	232,795,371	201,580,604

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

	2019 \$	2018 \$
Cash at bank and in hand	1,034,919	3,010,230
Short-term deposits	20,500,000	29,500,000
Total cash and cash equivalents	21,534,919	32,510,230

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 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 2.36% (2018: 2.55%).

#### 14. CURRENT ASSETS - RECEIVABLES

	2019 \$	2018 \$
Interest receivable	102,162	163,700
GST receivable <sup>1</sup>	91,736	119,758
Other <sup>1</sup>	101,888	110,274
Total current receivables	295,786	393,732

<sup>1</sup> These receivables are non-interest bearing, most of which have repayment terms between 30 and 60 days. There are no receivables with an expected credit loss.

#### 15. NON-CURRENT ASSETS - INVESTMENTS IN FINANCIAL ASSETS

	2019 \$	2018 \$
Listed Australian shares – at fair value	714,118	793,301

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

	Ownership I	Ownership Interest		Fair value <sup>1</sup>		Cost of investment	
Listed investments	2019 %	2018 %	2019 \$	2018 \$	2019 \$	2018 \$	
Non-current investments:2							
Antisense Therapeutics Ltd	1.24%	2.74%	233,579	254,766	1,582,535	3,106,944	
Optiscan Imaging Limited	1.76%	1.92%	480,539	538,535	786,131	786,131	
Total listed investments			714,118	793,301	2,368,666	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.

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

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

<sup>2</sup> A fair value increase of \$259,864 in the carrying value of investments (2018: decrease of \$354,935) has been made through other comprehensive income in the year due to an increase in their market value in the year.

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

	2019 \$	2018 \$
Equipment and furniture at cost		
Opening balance	107,333	74,454
Additions	18,070	34,417
Disposals	-	(1,538)
Closing balance	125,403	107,333
Accumulated depreciation		
Opening balance	(51,955)	(37,519)
Depreciation for the year	(19,898)	(15,461)
Disposals	-	1,025
Closing balance	(71,853)	(51,955)
Net carrying amount	53,550	55,378
Leasehold improvements at cost		
Opening balance	79,165	79,165
Closing balance	79,165	79,165
Accumulated depreciation		
Opening balance	(65,457)	(52,263)
Depreciation for the year	(13,195)	(13,194)
Closing balance	(78,652)	(65,457)
Net carrying amount	513	13,708
Total plant and equipment, net	54,063	69,086

#### 17. CURRENT LIABILITIES - PAYABLES

	2019 \$	2018 \$
Creditors (unsecured) 1	5,895,925	7,223,010
PAYG tax liability	56,017	52,495
Total current payables	5,951,942	7,275,505

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

#### 18. CURRENT LIABILITIES - PROVISIONS

	2019 \$	2018 \$
Annual leave	320,132	293,709
Long service leave	218,415	165,723
Total current provisions	538,547	459,432

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

	2019 \$	2018 \$
Long service leave	24,844	38,462

#### 20. CONTRIBUTED EQUITY

	2019 \$	2018 \$
(a) Ordinary shares		
Issued and fully paid at 30 June	113,021,993	98,403,149
Movement in ordinary shares:		
Opening balance	98,403,149	97,853,499
Issue of shares	12,629,777	549,650
Transfer from option reserve	1,989,067	_
	113,021,993	98,403,149
Ordinary shares on issue:	No:	No:
Opening balance	202,637,888	200,574,370
Issue of shares on exercise of quoted options	46,776,951	2,063,518
	249,414,839	202,637,888

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

Issued capital at 30 June 2019 amounted to \$113,021,993 (249,414,839 fully paid ordinary shares) net of share issue costs and tax. During the year the Company issued 46,776,951 ordinary shares on the exercise of quoted options for \$12,629,777. At 30 June 2019, the company had no quoted options on issue, all options had been exercised or expired by 25 November 2018. The fair value of the options at their issue date of \$1,989,067, originally recognised in the options reserve (note 21), was transferred to contributed equity.

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

#### Options granted to directors and employees

The company has two share based-payment schemes, the Long Term Incentive Plan 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 granted 8,844,000 options over ordinary shares under these plans during the year ended 30 June 2019 (note 28). These options had a weighted average fair value at their grant date of \$0.22 per 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. ACCUMULATED LOSSES AND RESERVES

	2019 \$	2018 \$
(a) Movements in accumulated losses were as follows:		
Balance at 1 July	(65,149,999)	(48,247,759)
Net loss for the period	(20,910,061)	(16,902,240)
Balance at 30 June	(86,060,060)	(65,149,999)
(b) Reserves		
Net unrealised gains reserve (i)	737,255	477,391
Share-based payments reserve (ii)	3,420,349	2,452,838
Option reserve (iii)	-	1,989,067
Total reserves	4,157,604	4,919,296
(i) Movement in net unrealised gains reserve:		
Opening balance	477,391	832,326
Unrealised gains/(losses) on investments in financial assets	259,864	(354,935)
Closing balance	737,255	477,391
(ii) Movement in share-based payments reserve:		
Opening balance	2,452,838	2,064,831
Share based payments expense	967,511	388,007
Closing balance	3,420,349	2,452,838
(iii) Movement in option reserve:		
Opening balance	1,989,067	1,989,067
Transferred to contributed equity	(1,989,067)	-
Closing balance	_	1,989,067

#### (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.

#### 21. ACCUMULATED LOSSES AND RESERVES (CONT.)

#### 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.

#### 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 was recognised in the option reserve. The same amount, \$1,989,067, was transferred to contributed equity on 25 November 2018 following the expiry of all quoted options. The balance on the option reserve at 30 June 2019 was nil.

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

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

The Group 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 two 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 at 30 June 2019.

At 30 June 2019, 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 im	Cost of investment		
Judgements of reasonably possible movements	2019 \$	2018 \$	2019 \$	2018 \$
+ 0.50% (50 basis points) (2017: + 0.50%)	71,903	103,403	-	-
- 0.50% (50 basis points) (2017: - 0.50%)	(71,903)	(103,403)	-	_

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

The post tax figures include an offset for unrecognised tax losses (bringing the tax effect to nil) for the year ended 30 June 2019 (2018: Nil).

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 investments in 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 2019, 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 of loss after tax	Impact on equity after tax
Judgements of reasonably possible movements	2019 \$	2019 \$	2018 \$	2018 \$
Change in variables				
10% increase in listed share price	49,988	49,988	55,531	55,531
10% decrease in listed share price	(49,988)	(49,988)	(55,531)	(55,531)

#### (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:

	Consolidated				
2019	USD	EURO	GBP	CAD	
	2019 \$	2019 \$	2019 \$	2019 \$	
Financial assets					
Cash	551,719	-	_	-	
Receivables	101,888	-	_	_	
Financial liabilities					
Payables	(5,135,089)	-	(51,269)	(4,351)	
Net exposure	(4,481,482)	-	(51,269)	(4,351)	

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

	Consolidated				
	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)	

The following sensitivity is based on the foreign currency risk exposures in existence at 30 June 2019.

At 30 June 2019, 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:

Judgements of reasonably possible movements	Post tax (loss)/ profit impact		Cost of investment	
	2019 \$	2018 \$	2019 \$	2018 \$
Consolidated				
AUD/USD +10% (2017: +10%)	285,185	319,556	_	-
AUD/USD -10%	(348,560)	(390,568)	_	_
AUD/Euro +10% (2017: +10%)	_	2,421	_	_
AUD/Euro –10%	-	(2,959)	_	_
AUD/GBP +10% (2017: +10%)	3,263	14,773	_	_
AUD/GBP –10%	(3,988)	(18,056)	_	_
AUD/CAD +10% (2017: +10%)	277	461	_	_
AUD/CAD -10%	(388)	(564)	_	_

The reasonably possible movements at 30 June 2019 are lower than at 30 June 2018 due mainly to the lower 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 financial liabilities of the Group relate to trade payables that are all expected to be paid within 12 months.

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. The Group does not have any derivative investments where the fair value is estimated using inputs other than quoted prices 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 where 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 investment in 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 2019 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 e % equity i	
Name of company	2019 %	2018 %
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.

#### 24. CASH FLOW STATEMENT RECONCILIATION

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

	2019 \$	2018 \$
Cash at bank and in hand (note 13)	21,534,919	32,510,230
	21,534,919	32,510,230
(b) Reconciliation of net loss after tax to net cash flows from operations		
Net loss for the year	(20,910,061)	(16,902,240)
Adjustments for:		
Income tax benefit recognised in profit or loss	(14,636,973)	(12,017,248)
Depreciation of non-current assets	33,093	28,655
Net loss on disposal of non-current assets	-	513
Share-based payments	967,511	388,007
Net exchange differences	(259,092)	156,433
	(13,895,465)	(11,443,640)
Changes in:		
Receivables	97,946	115,234
Prepayments	(132,346)	(138,300)
Payables	(1,427,978)	5,648,211
Provisions	65,497	73,420
Net cash used in operating activities	(36,202,400)	(22,647,315)
Income tax refund	12,017,247	2,709,765
Net cash generated by operating activities	(24,185,156)	(19,937,550)

#### 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. A new lease commenced on 15 July 2019 for a period of three years for the same premises.

	2019 \$	2018 \$
Within one year	7,029	109,442
After one year but not more than five years	_	10,963
	7,029	120,405

#### (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:

	2019 \$	2018 \$
Within one year	7,776,947	24,340,889
After one year but not more than five years	85,446	1,982,603
After more than five years	128,169	182,260
	7,990,562	26,505,752

#### 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 \$364,563 (2018: \$NIL) and those which could become payable in more than one year total \$16,363,559 (2018: \$15,834,654). 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 2019 in respect of a rental deposit for its office premises of \$43,841 (2018: \$43,841).

#### 27. KEY MANAGEMENT PERSONNEL

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

	2019 \$	2018 \$
Short-term employee benefits	1,002,359	993,780
Post employment benefits	95,225	94,409
Share-based payments expense	752,306	196,723
Total compensation	1,849,890	1,284,912

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:

	2019 \$	2018 \$
Expense arising from equity-settled share-based payment transactions:		
Director and employee services received	967,511	388,007

#### (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 and are not transferable. 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 – director FY2019	29 November 2018	\$0.20	\$0.855	29 November 2022	29 November 2019
LTIP – employees	31 March 2016	\$0.24	\$0.48	1 January 2022	1 January 2017
LTIP – employees FY2018	23 August 2017	\$0.33	\$1.16	1 January 2023	30 June 2018
LTIP – employees FY2019	3 April 2019	\$0.26	\$0.855	3 April 2023	3 April 2020
NED Plan	7 March 2016	\$0.19	\$0.48	7 March 2021	30 June 2016
NED Plan FY2019	29 November 2018	\$0.20	\$0.855	29 November 2022	29 November 2019

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

#### (c) 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 4 or 5 years.

LTIP – director FY2019         \$0.57         \$0.855         \$0.20         58%         4 years         0%         2.04%         Bind           LTIP – employees         \$0.70         \$0.48         \$0.24         65%         5 years         0%         2.09%         Bind           LTIP – employees FY2018         \$0.43         \$1.16         \$0.32         66%         5 years         0%         2.09%         Bind           LTIP – employees FY2019         \$0.67         \$0.855         \$0.26         57%         4 years         0%         2.04%         Bind           NED Plan         \$0.38         \$0.48         \$0.19         65%         5 years         0%         2.09%         Bind		Grant date share price	Exercise price	Fair value per option	Expected volatility	Option life	Dividend yield	Risk free interest rate	Model used
LTIP - employees         \$0.70         \$0.48         \$0.24         65%         5 years         0%         2.09%         Bind           LTIP - employees FY2018         \$0.43         \$1.16         \$0.32         66%         5 years         0%         2.09%         Bind           LTIP - employees FY2019         \$0.67         \$0.855         \$0.26         57%         4 years         0%         2.04%         Bind           NED Plan         \$0.38         \$0.48         \$0.19         65%         5 years         0%         2.09%         Bind	LTIP - director	\$0.38	\$0.48	\$0.19	65%	5 years	0%	2.09%	Binomial
LTIP – employees FY2018         \$0.43         \$1.16         \$0.32         66%         5 years         0%         2.09%         Bind           LTIP – employees FY2019         \$0.67         \$0.855         \$0.26         57%         4 years         0%         2.04%         Bind           NED Plan         \$0.38         \$0.48         \$0.19         65%         5 years         0%         2.09%         Bind	LTIP – director FY2019	\$0.57	\$0.855	\$0.20	58%	4 years	0%	2.04%	Binomial
LTIP - employees FY2019         \$0.67         \$0.855         \$0.26         57%         4 years         0%         2.04%         Bind           NED Plan         \$0.38         \$0.48         \$0.19         65%         5 years         0%         2.09%         Bind	LTIP – employees	\$0.70	\$0.48	\$0.24	65%	5 years	0%	2.09%	Binomial
NED Plan \$0.38 \$0.48 \$0.19 65% 5 years 0% 2.09% Bind	LTIP – employees FY2018	\$0.43	\$1.16	\$0.32	66%	5 years	0%	2.09%	Binomial
	LTIP – employees FY2019	\$0.67	\$0.855	\$0.26	57%	4 years	0%	2.04%	Binomial
NED Disp EV2010	NED Plan	\$0.38	\$0.48	\$0.19	65%	5 years	0%	2.09%	Binomial
NED Plati F 12019 \$0.07 \$0.000 \$0.20 30% 4 years 0% 2.04% Billion	NED Plan FY2019	\$0.57	\$0.855	\$0.20	58%	4 years	0%	2.04%	Binomial

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

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

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

Number options ad rights	Weighted average exercise price	Number of options	Weighted average exercise price
_	<u> </u>	and rights	\$
,075,000	0.46	10,575,000	0.46
,844,000	0.855	500,000	1.16
_	-	(1,000,000)	0.26
_	-	-	_
,919,000	0.67	10,075,000	0.51
905,000	0.50	8,847,500	0.49
, ;	075,000 844,000 - - - ,919,000	075,000 0.46 844,000 0.855   ,919,000 0.67	075,000

The share options outstanding at the end of the year had a weighted average exercise price of \$0.67 (2018: \$0.51) and a weighted average remaining contractual life of 716 days (2018: 1,091 days).

#### 29. NET TANGIBLE ASSET BACKING

	2019 \$	2018 \$
Net tangible asset backing per ordinary security	0.12	0.19

#### 30. AUDITORS' REMUNERATION

The auditor of Opthea Limited is Deloitte Touche Tohmatsu.

	2019 \$	2018 \$
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
	84,565	89,065

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

On 7 August 2019 the Company announced the results of its Phase 2b trial of OPT-302 in wAMD patients. The trial met the pre-specified primary endpoint of superiority in mean visual acuity gain at 24 weeks compared to the standard of care monotherapy. This result provides commercial justification for the Group to prepare for registrational Phase 3 trial activities and evaluation of all strategic and corporate options.

Except for this event, 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

	2019 \$	2018 \$
Current assets	36,279,568	44,557,305
Non-current assets	768,181	862,387
Total assets	37,047,749	45,419,692
Current liabilities	(6,368,040)	(7,761,758)
Non-current liabilities	(24,844)	(39,396)
Total liabilities	(6,392,884)	(7,801,155)
Net assets	30,654,865	37,618,537
Issued capital	113,021,993	98,403,149
Retained earnings	(86,524,732)	(65,703,906)
Option reserve	-	1,989,067
Employee equity benefits reserve	3,420,349	2,452,837
Net unrealised gains reserve	737,255	477,391
Total shareholders' equity	30,654,865	37,618,537

#### (b) Financial performance

	Year ended 30 June 2019 \$	Year ended 30 June 2018 \$
Loss of the parent entity	(20,820,825)	(16,739,594)
Other comprehensive income/(expense)	259,864	(354,935)
Total comprehensive loss of the parent entity	(20,560,961)	(17,094,529)

#### (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 2019 (2018: Nil).

#### (d) Parent entity contingent liabilities

The parent entity had a bank guarantee outstanding at 30 June 2019 in respect of a rental deposit for its office premises of \$43,841 (2018: \$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 2019

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 2019 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 2019.

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 9 August 2019 **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 2019, 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 2019 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.

#### **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

## INDEPENDENT AUDITOR'S REPORT (CONT.)

#### **Deloitte**

#### **Key Audit Matter**

### Authorisation and classification of expenses

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 20198, Opthea continued its clinical development program including 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 advancement of the clinical trials resulted in an 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
- 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.

#### 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.

## INDEPENDENT AUDITOR'S REPORT (CONT.)

#### 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 14 to 20 of the Directors' Report for the year ended 30 June 2019.

In our opinion, the Remuneration Report of Opthea Limited, for the year ended 30 June 2019, 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.

#### DELOITTE TOUCHE TOHMATSU

DELOITTE TOUCHE TOHMATSU

Samuel Vorwerg Partner

Chartered Accountants Melbourne, 9 August 2019

### ASX ADDITIONAL INFORMATION

#### 1. DISTRIBUTION OF EQUITY SECURITIES

The number of shareholders, by size of holding, of quoted fully paid ordinary shares as at 1 August 2019 is as follows:

	Fully paid ordinary shares	
Category	No. of holders	No. of shares
1 – 500	116	22,855
501 – 1,000	381	349,983
1,001 – 5,000	1,146	3,048,823
5,001 – 10,000	460	3,548,702
10,001 – 100,000	628	19,716,308
100,001 – 9,999,999,999	110	222,728,168
Total	2,841	249,414,839
Number of shareholders holding less than a marketable parcel of shares	145	39,313

#### 2. TWENTY LARGEST SHAREHOLDERS

The names of the 20 largest holders of quoted fully paid ordinary shares and their respective holdings at 1 August 2019 are:

Rank	Name	No. of shares	% interest
1	HSBC Custody Nominees (Australia) Limited	67,756,601	27.17%
2	Citicorp Nominees Pty Limited	38,186,157	15.31%
3	UBS Nominees Pty Ltd	15,254,372	6.12%
4	Jagen Pty Ltd	13,020,540	5.22%
5	Armada Trading Pty Limited	11,721,967	4.70%
6	National Nominees Limited	6,687,922	2.68%
7	J P Morgan Nominees Australia Pty Limited	6,662,381	2.67%
8	Warbont Nominees Pty Ltd	6,495,502	2.60%
9	Merrill Lynch (Australia) Nominees Pty Limited	6,364,916	2.55%
10	BNP Paribas Nominees Pty Ltd	5,461,912	2.19%
11	Mrs Margaret Lynette Harvey	3,302,000	1.32%
12	Ludwig Institute For Cancer Research Ltd	3,122,090	1.25%
13	Just Group Investment Pty Ltd	2,184,559	0.88%
14	LI Family Nominees Pty Ltd	2,150,538	0.86%
15	Sandhurst Trustees Ltd	1,910,259	0.77%
16	Montoya Pty Ltd	1,899,543	0.76%
17	LGL Trustees Limited	1,419,693	0.57%
18	Octavian Services Pty Ltd	1,285,715	0.52%
19	CS Fourth Nominees Pty Limited	1,167,583	0.47%
20	Chemical Trustee Limited	1,158,108	0.46%
	Totals: Top 20 holders of ordinary fully paid shares	197,212,358	79.07%
	Total remaining holders balance	52,202,481	20.93%

### ASX ADDITIONAL INFORMATION (CONT.)

#### 3. SUBSTANTIAL SHAREHOLDERS

The following information is current at 1 August 2019 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	37,705,918
Regal Funds Management Pty Ltd	24,551,444
Jagen Pty Ltd	18,202,068
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 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. (Non-Executive Director)

#### **COMPANY SECRETARY**

Mike Tonroe

BSc(Hons) FCA MAICD

#### REGISTERED OFFICE

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

#### **Principal Administrative Office**

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

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#### **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).

