

# HOPE IS ON THE HORIZON

ANNUAL REPORT 2022 - 2023

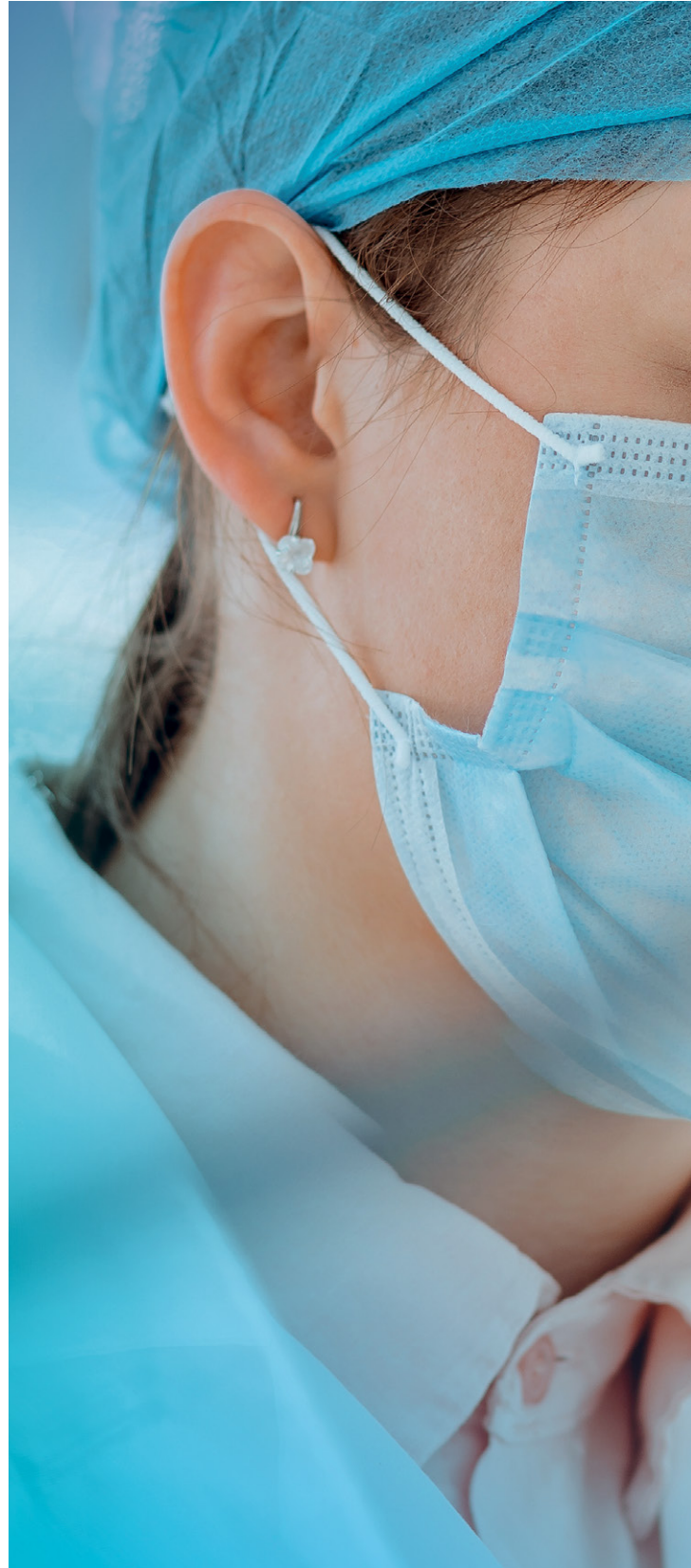
## Our cover

Our lead drug candidate Sozinibercept (OPT-302) has the potential to become the first selective VEGF-C/D inhibitor for the treatment of wet AMD.



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## ABOUT OPTHEA

Opthea is a clinical stage biopharmaceutical company committed to developing innovative therapies to improve vision in patients with retinal eye diseases. With an established foundation in Australia and expanded presence in the United States following our listing on the NASDAQ stock exchange in October 2020, we are well positioned to advance our lead therapeutic candidate sozinibercept (OPT-302) through Phase 3 clinical trials in support of future registration filings for marketing approval and commercialization.

Our first-in-class novel therapeutic called sozinibercept (OPT-302), is a VEGF-C/D “trap”, to be used in combination with standard of care anti-VEGF-A therapies to improve vision in patients, many of whom respond sub-optimally or become refractory to existing treatments.

Millions of people around the world suffer from impaired vision as a result of the aging process. With limited treatment options currently available for patients, and a large unmet medical need, our mission is to expeditiously develop our therapies to improve visual outcomes for patients, leading to better quality of life.

### OUR VISION

Advancing bold therapeutic innovation and inspiring transformation in the global retinal community

### OUR MISSION

Dedicated to improving and protecting vision in people with retinal diseases

# OUR JOURNEY



1985

Circadian Technologies listed on the Australian Securities Exchange in 1985.



2008

Circadian focused its strategy to concentrate on the development of biologics-based therapies.



2015

The company was renamed Opthea Limited and began developing OPT-302 for retinal eye diseases.

Initiated Phase 1/2A Clinical Trial in wet AMD.



2019

Opthea announces positive data from a Phase 2b trial of OPT-302 in patients with wet AMD.



2020

Opthea began trading on the Nasdaq under the ticker symbol "OPT."

Announced results of Phase 2 Clinical Trial in Diabetic Macular Edema.



## FY22-23 HIGHLIGHTS



Continued to execute on global patient recruitment strategies in North America, Europe, Asia Pacific and Latin America with enhanced site and physician engagement to advance sozinibercept ShORE and COAST Phase 3 clinical studies in wet AMD.



Achieved approximately 75% patient enrolment in our Phase 3 clinical trials in August 2023. We anticipate completion of patient enrolment for COAST and ShORE in the first and second quarter of calendar year 2024 respectively.



Maintained our commitment to strong engagement with the international retina clinical communities by actively participating and presenting at important clinical and corporate meetings, symposia and events, including the American Academy of Ophthalmology (AAO), EURetina, Ophthalmology Innovation Summit (OIS), American Society Retina Specialists (ASRS), and FLOretina conferences.



Added new appointments to further strengthen the leadership team, Board of Directors and global operations supporting the pivotal Phase 3 program.



Published Opthea's Phase 2b study results of combination sozinibercept with Lucentis® (ranibizumab) for the treatment of wet age-related macular degeneration in *Ophthalmology*, the leading peer-reviewed journal of the American Academy of Ophthalmology.



Advanced manufacturing, non-clinical toxicology and bioanalytical regulatory studies in support of the ongoing Phase 3 clinical trials, planned BLA filing and future commercial launch for sozinibercept which has Fast-Track Designation from the FDA for wet AMD.



Successfully completed a non-dilutive financing transaction for up to US\$170 million and a US\$90 million equity financing, bolstering Opthea's financial and strategic position to maximize the value of sozinibercept.



2021

Initiated Phase 3 ShORE and COAST Clinical Trials in wet AMD.



2022

Opthea executed a non-dilutive financing transaction for up to US\$170 million from Carlyle and Abingworth.

## TRIAL HIGHLIGHTS



The two pivotal OPT-302 Phase 3 clinical trials each have over 185 activated sites globally.



Approximately 35 countries around the world are recruiting treatment naive patients for our Phase 3 program.

# SOZINIBERCEPT PROGRESSING IN GLOBAL WET AMD PHASE 3 TRIALS

Wet AMD affects over 3.5 million people in the US and Europe. Sozinibercept (OPT-302) has demonstrated meaningful, improved visual outcomes in its Phase 2b studies. These results bring us closer to helping a large and growing wet AMD population.

We are progressing our two concurrent, global, randomized, sham-controlled Phase 3 clinical studies:

- **ShORe:** Study of sozinibercept (OPT-302) in combination with Ranibizumab; and
- **COAST:** Combination sozinibercept (OPT-302) with Aflibercept Study.

The ShORe and COAST Phase 3 trials build upon and maintain key features of our successful Phase 2b clinical trial of sozinibercept combination therapy for the treatment of wet AMD. Both Phase 3 studies evaluate sozinibercept as a combination therapy over a 52-week treatment period, each with 990 patients.

The primary endpoint of the Phase 3 studies is the mean change in best corrected visual acuity (BCVA) from baseline to week 52 for sozinibercept combination therapy compared to standard of care anti-VEGF-A monotherapy.

## Why sozinibercept?

Current standard of care treatments for wet AMD are largely limited to VEGF-A inhibitors such as ranibizumab (Lucentis®) or aflibercept (Eylea®). These standard of care treatments are administered monthly or every other month by intravitreal injection. Although patients are offered some vision benefit, most patients fail to achieve sufficient vision gains to resume routine daily activities such as driving and reading. Often wet AMD patients experience further vision loss after 12 months.

Recent and current clinical trials in the wet AMD landscape have focused on achieving increased durability of therapy, measured by longer treatment intervals, without aiming

to improve visual outcomes. By contrast, our successfully completed Phase 2b study data has demonstrated sozinibercept (OPT-302) combination therapy offers superior vision gain over the current standard of care for wet AMD with comparable safety.

The design of ShORe and COAST have been optimized based on Phase 2b outcomes to maximize probability of success and commercial opportunity for sozinibercept (OPT-302).

## Recruitment for Phase 3 studies

We have been actively recruiting patients globally for participation in both ShORe and COAST Phase 3 studies. As of August 2023, over 185 clinical trial sites for each study have been activated in the United States ("US"), Canada, Europe Asia Pacific and Latin America.

Over the next year, we will continue to work with a global Clinical Research Organization or "CRO" to complete patient recruitment with a target completion of patient enrolment for COAST in the first quarter of calendar year 2024 and for ShORe in the second quarter of calendar 2024.

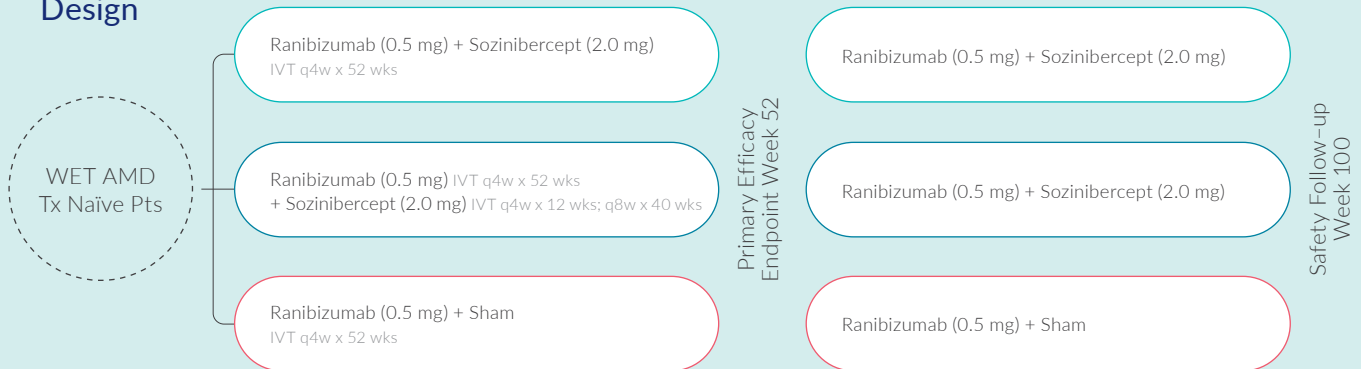
## Completing Phase 3 studies

The ShORe and COAST studies are both double-masked, sham-controlled Phase 3 registrational trials to evaluate efficacy and safety of intravitreal 2.0 mg sozinibercept in combination with either 0.5 mg ranibizumab (Lucentis®), or 2.0 mg aflibercept (Eylea®) respectively.

Each study will investigate the mean change in best corrected visual acuity from baseline to week-52 for sozinibercept combination therapy versus standard of care anti-VEGF-A monotherapy alone. Topline data for the primary endpoint is expected to be reported when all patients complete the 52-week treatment period and the results are collected, analyzed and verified.

If the topline results at the completion of the primary efficacy phase are favorable, we intend to file for marketing approval for sozinibercept for the treatment of wet AMD in the US as a priority followed by filing in the European Union ("EU").

## ShORe Trial Design



## COAST Trial Design



## Fast-Track development timeline

Superior Phase 2b results led to the US FDA granting Fast-Track designation to sozinibercept as a combination therapy for the treatment of patients with wet AMD. Fast-Track designation is designed to expedite drug development and review to get important new therapies with an unmet medical need to patients more quickly. If our Phase 3 trials are successful, Opthea plans to file Biologics License and Marketing Authorization Applications with regulatory agencies in the US and the EU respectively.

## Commercial advantages

Investigation of sozinibercept (OPT-302) as a combination therapy with two leading standard of care treatments may position sozinibercept as a complementary treatment for administration with any VEGF-A inhibitor. Importantly, our Phase 3 trials ShORe and COAST are designed to

demonstrate superior visual acuity outcomes of sozinibercept combination treatment over standard of care anti-VEGF-A monotherapy. This approach differentiates Opthea's clinical development program from the majority of other clinical programs for wet AMD which are mainly focused on demonstrating durability of anti-VEGF-A therapy to reduce treatment burden.

## A global Phase 3 program

The two pivotal sozinibercept (OPT-302) Phase 3 clinical trials each have over 185 clinical trial sites activated globally. ShORe and COAST are currently recruiting patients with treatment naïve wet AMD in approximately 35 countries around the world.



# DR. CHARLES WYKOFF

Chief Investigator  
Phase 3 COAST Study

## Q: Could you provide an overview of your background?

I am a medical and surgical retina specialist based in Houston, Texas. Upon completing both my MD and PhD, I decided to pursue a career in clinical research. I am actively involved in leading clinical trials as part of Retina Consultants of Texas, and I lead the Research Committee for Retina Consultants of America, representing over 250 retina specialists across the US. I also hold the position of Deputy Chair of Ophthalmology and serve as an Associate Clinical Professor at Blanton Eye Institute, which is affiliated with Weill Cornell Medical School.

## Q: Briefly characterize your current clinical practice setting?

In my practice of about 20 retina specialists, we focus entirely on vitreoretinal diseases seeing on average 60 patients per day. We see a variety of cases including those requiring surgical procedures. In addition, many of our patients receive routine anti-VEGF-A injections, which work effectively but require ongoing treatment. A significant portion of our practice comprises patients requiring these chronic anti-VEGF-A injections.

### Question

How prevalent is wet AMD in your practice?

### Dr Wykoff

From the average of 60 patients per day, up to 12 would be new cases. From the remainder, about 70% are going to be patients that are receiving injections for a chronic condition like wet AMD and other conditions. It's a large bulk of our practice, and I think that's pretty consistent across the US.

## Q: How do your patients react to being diagnosed with wet AMD?

When delivering the diagnosis of wet AMD, the reactions from patients vary. Most patients are anxious and have heard about the condition from friends or family. Many are concerned about the possibility of blindness and some fear the treatment itself. We must understand and address this fear in order to most appropriately help the patient.

When discussing treatment options, patients value the prospect of visual improvement, which brings hope. Even if visual acuity only shifts slightly, it can have a meaningful impact on individual patients.

## Q: From your perspective what is the current unmet need in wet AMD?

There are two common unmet needs actively being investigated in ongoing wet AMD trials that are also relevant to many other exudative retinal diseases. The first is identifying new targets that can complement, enhance or extend the effects of VEGF-A inhibitors, and the second is treatment burden. Addressing these needs is crucial for advancing treatments and improving outcomes for patients with wet AMD. Ultimately, when you talk to patients, the overarching focus is that they want to see better, and many are actually willing to accept a greater treatment burden to optimize their visual function.

## Q: Are there current limitations to the current standard of care?

Anti-VEGF-A monotherapy is the standard of care in wet AMD, which requires frequent injections, leading to a high treatment burden in many patients. Patients often switch between different anti-VEGF-A therapies in pursuit of better outcomes. The high rate of switching, around 40%, indicates an unmet need for improved treatment options that optimize vision for patients. Improved visual gain remains a significant unmet need, and while the field is actively exploring new molecular targets, no other approved target has demonstrated the ability to add additional vision beyond simple VEGF-A inhibition. Addressing these limitations is crucial to providing more effective and less burdensome treatments for patients with wet AMD.



**Q: How long have you been involved with sozinibercept (OPT-302) and what excites you about the therapy?**

Sozinibercept (OPT-302) is an extremely exciting program to me. I've been involved since 2018, and what excites me the most is its potential to add vision to the current standard of care for wet AMD patients worldwide. It's the only program in late-stage development that aims to truly enhance visual function in combination with maximal VEGF-A suppression by blocking additional relevant cytokines in patients. While many other treatments focus on durability the sozinibercept (OPT-302) trials seek to demonstrate a further gain in visual function. Fully blocking the VEGF-A, -C and -D signalling pathways may offer the most optimized treatment for wet AMD patients to preserve and improve vision. It's a challenging endeavour, but if successful, it would bring significant value to the field and greatly benefit patients with wet AMD.

**Q: What are your thoughts on the completed and ongoing clinical trials for sozinibercept (OPT-302)?**

Sozinibercept (OPT-302) has the most compelling efficacy data seen in wet AMD on top of the standard of care. The Phase 2b trial data showed a meaningful improvement in visual acuity with sozinibercept (OPT-302) in addition to ranibizumab. The Phase 3 trial designs are superiority trials over standard of care alone to show maximum benefit of blocking multiple members of the vascular endothelial growth factor (VEGF) signalling pathway. The Phase 3 trials are more challenging due to the high bar for superiority, aiming to gain more visual function. This new mechanism of action holds great potential to improve visual outcomes for wet AMD patients.

**Q: Could you comment on using an additional injection of sozinibercept (OPT-302) for the potential management of patients in your practice?**

In my practice, we already routinely and successfully manage two sequential injections on the same day for other medications. Potentially incorporating sozinibercept (OPT-302) into our routine flow appears quite feasible. Sozinibercept (OPT-302) has demonstrated a well-tolerated safety profile to date, comparable to standard of care.

While it requires some additional preparation, I believe it has potential to be a meaningful addition to our treatment options.

**Q: Can you comment on the designs of the sozinibercept (OPT-302) Phase 3 clinical trials?**

The Opthea team's efforts to create a Phase 3 program with global participation, showcases their dedication and ability to execute these ambitious studies. The decision to have two separate trials, one with aflibercept and the other with ranibizumab in the Phase 3 trial was a strong and confident move, demonstrating that sozinibercept (OPT-302) aims to be effective with any anti-VEGF-A agent.

While some patients may be interested in participating in this clinical trial, these trials were intentionally designed to enrol patients with meaningful vision loss to assess the full benefit of sozinibercept (OPT-302) in combination with VEGF-A inhibition. However, the hypothesis is that all patients with wet AMD would benefit from combination therapy if the trial is successful. The trial's design ensures meaningful data interpretation while expecting broad applicability for all wet AMD patients.

**Q: How does the sozinibercept (OPT-302) Phase 3 program compare with other wet AMD studies you have been involved in?**

The Phase 3 program for sozinibercept (OPT-302) stands out from other wet AMD studies I've been involved in because it offers a compelling efficacy-related value proposition to patients. The trial's objective of improving vision through a combination therapy with the current standard of care resonates well with patients. They are eager to participate, as many patients find the idea of contributing to a greater good and advancing medical knowledge powerful and meaningful. The Phase 3 trials for sozinibercept (OPT-302) offers patients hope and excitement for better vision outcomes for those suffering from wet AMD.

**Q: What is your perspective on working with Opthea?**

Working with the Opthea team on their global Phase 3 clinical trial program has been inspiring. In my perspective, Opthea has a distinct personality and ethos. They have shown a can-do attitude and a determination to punch above their weight class. This speaks directly to the culture and ambition of Opthea.

The Company has chosen to build their reputation on a firm foundation of the quality of their clinical trials. Their dedication to sound science reflects positively on the Company and the value they bring to the field.

**Q: How do you unwind away from the clinic?**

When I'm away from the clinic, I focus on family. I have three kids – one in college, one in high school and one in middle school. Our family has a bunch of favorite quotes including "You can do almost anything in life, just not all at the same time." I'm passionate about clinical trials and program development but spending time with my family is also a priority. We love outdoor activities like hiking, biking, and traveling together. Recently, my youngest son and I have taken up indoor rock climbing as a shared hobby. Balancing work and family life brings me fulfilment and joy.



# PROFESSOR TIMOTHY JACKSON

Chief Investigator  
Phase 3 ShORe Study

**Q: Can you describe your journey to achieving extensive experience in Ophthalmology?**

After attending medical school in New Zealand, I pursued my postgraduate ophthalmology residency and vitreoretinal fellowship based at Moorfields Eye Hospital in the United Kingdom (UK), along with a PhD at St Thomas' Hospital, London. Currently, I am Professor of Retinal Research at King's College London, leading undergraduate ophthalmology teaching covering some of the big central London hospitals. Over the past decade I've also contributed to the Interventional Procedures Advisory Committee (IPAC) for the National Institute of Health and Care Excellence (NICE), evaluating novel device and surgical techniques.

**Q: What is your day-to-day workload?**

I wear three main hats. Firstly, I dedicate 50% of my time to National Health Service (NHS) appointments and surgery, attending to patients at Kings College Hospital. We handle challenging cases of retinal diseases in underserved patients from poorer inner-city areas. Secondly, I run a central London private practice, spending a day per week on surgery and clinics. Lastly, I devote the remaining time to an academic position running research grants, supervising clinical PhD students, and leading some large UK and European retinal device and surgical trials for age-related macular degeneration (AMD).

**Q: What are the current unmet need(s) in the management of wet AMD?**

In the UK, issues stem from limited resources and the challenge of keeping up with the increasing prevalence of this common disease. While anti-VEGF-A therapies have shown significant benefits compared to earlier treatments, there is a desire for an improved approach, as patients have been on these treatments for many years and want something new. The goal is to find a treatment that can maintain or improve visual acuity more effectively, providing substantial and lasting gains, with infrequent administration, to enhance both patient comfort and long-term vision.

**Question**

**How do you talk with your patients about being diagnosed with wet AMD?**

**Dr Tim Jackson**

When delivering a diagnosis of wet AMD to patients, it is a deeply personal and critical moment as a doctor. Patients arrive already suspecting something serious due to prior symptoms and visits to optometrists. Their main fear revolves around going blind, and addressing this fear is essential. In most cases, doctors can honestly reassure patients that they will not lose all vision, emphasizing visual acuity in the other eye. However, it becomes more challenging when patients are already receiving treatment for one eye and then develop wet AMD in the fellow eye, raising the stakes significantly.

Understanding the impact of wet AMD on patients' lives is an ongoing challenge. Doctors discuss treatment and visual prognosis during appointments, but they often lack insight into the daily reality for patients, like the frustration of being unable to read books due to vision loss. Questionnaires and assessments can provide further understanding, but further research is needed to gain a comprehensive understanding of the broader impact of wet AMD.

**Q: How do you address a patient with anxieties about treatment for wet AMD?**

The anxiety surrounding wet AMD treatments can affect how patients perceive vision gains. While gaining seven or eight letters on an eye chart may seem substantial, it's not an improvement from their healthy baseline but a recovery from previously lost vision. These patients experience a gradual increase after losing vision suddenly. The anxiety of potential vision loss remains even after treatment, impacting the overall perception of improvement in quality of life.

**Q: How long have you been involved with the sozinibercept (OPT-302) clinical program?**

I have been involved with the clinical development of sozinibercept (OPT-302) since 2018. We initially participated as a recruiting site for the Phase 2b trial in wet AMD. Since then, the program has grown, and I find it highly fulfilling to be part of a potential novel treatment that shows promise. While we cannot predict the outcome of the next Phase 3 trial phase, the Phase 2b trial was crucial, as it offered the potential for improved visual acuity, something not provided by other treatments. The journey is ongoing, but significant progress has been achieved so far.

**Q: What is your assessment on targeting inhibition of VEGF-C and VEGF-D with sozinibercept (OPT-302), and the results from the Phase 2b trial in wet AMD ?**

The concept of fully blocking VEGF-C and -D alongside VEGF-A in wet AMD makes physiological and mechanistic sense. Preclinical data has shown that suppressing VEGF-A can lead to elevated VEGF-C and -D levels, indicating the need for a multi-therapy approach. The phase 2B clinical trial results were compelling, demonstrating a statistically clear signal of efficacy. The robust trial design, of a randomized, double-masked, and sham-controlled study, ensured the integrity of the findings and makes the positive outcome promising.

**Q: What are your thoughts on using an additional injection of sozinibercept (OPT-302) with standard of care?**

When I was first introduced to the idea of regular anti-VEGF-A injections, many of us were sceptical about patient acceptance. However, over time, we have seen that patients adapt to and tolerate these injections well. Going from no treatment to one injection is a significant step, whereas adding a second injection during the same visit is much more manageable. Patients are already prepped and accustomed to the injection process, so an additional injection becomes less daunting. While it would be ideal to combine the drugs into a single injection, the efficacy demonstrated in a definitive trial would outweigh any concerns about giving two injections. Patients prioritise

improved vision and would likely accept the convenience of a second injection during the same visit, especially considering the time and effort saved by avoiding multiple clinic visits. In the UK, patients generally accept this approach for better vision outcomes.

**Q: What are your impressions of the sozinibercept (OPT-302) Phase 3 trial designs and the recruitment process at your clinic?**

The Phase 3 trial designs for sozinibercept combination therapy have been measured, closely mirroring the Phase 2b trial to avoid introducing uncertainties and risks. This caution means the trials are anticipated to yield consistent results to the existing data.

In my clinic, we are precise in selecting eligible patients who are likely to benefit. Recruitment has not been as difficult as anticipated, as the prospect of a second injection has not been a major barrier for patients. Many patients are willing to accept the additional injection for the potential of better visual acuity. In our selection, we aim for a successful result that benefits patients with wet AMD.

**Q: How have you found working with Opthea?**

I find Opthea to be a nimble organisation with a vision and a willingness to listen to input from clinical leads. It's enjoyable to be involved in decision-making processes, even if the final decisions are not mine to make. I've been impressed by how good they operate as a team.

The retina space is currently filled with dynamic research and sozinibercept (OPT-302) is a massively positive development in the space. A successful Phase 3 outcome will likely have this emerging technology seen by a large audience.

**Q: What gives you energy, and keeps you excited outside of your practice?**

I enjoy running twice a week, which provides a refreshing break from the pressures of work and screen time. During lockdown, I ran a marathon and learned sailing at a novice level, finding joy in these new experiences. Participating in NHS racing on a big sailing boat taught me valuable lessons about teamwork and learning from more experienced individuals. These activities not only enrich my life but also influence my approach to leadership and teamwork in the operating theatre.



## CHAIRMAN'S LETTER

The execution of the pivotal phase 3 studies of sozinibercept remained the focus for Opthea in the 2023 fiscal year. Despite the commercial success of several VEGF-A inhibitors, which are considered the standard of care for patients with Age-Related Macular Degeneration or wet AMD, more than half of patients cannot drive, read or live independently. At Opthea we are seeking to add sozinibercept to this standard of care to improve vision in all patients with wet AMD.

We began the 2023 fiscal year with the completion of a non-dilutive funding agreement with the Carlyle/Abingworth Group to provide US\$120 million for the development of sozinibercept for the treatment of wet AMD. We are pleased that a co-investor of Carlyle/Abingworth intends to invest an additional US\$50 million under the agreement, bringing the total to US\$170 million although this remains subject to final diligence and receipt of regulatory and tax approvals and we may not receive the additional US\$50 million. We continue to leverage the expertise provided by Carlyle/Abingworth through their affiliate, Launch Therapeutics, by working with the team for the execution of the phase 3 studies and the preparation for the completion of enrolment and analysis of the top-line data. Alongside the funding agreement, we raised US\$90 million through an equity financing. Subsequent to year end we raised an additional approximately US\$58 million which was supported by both domestic and overseas institutional investors. Proceeds from the funding agreement and the equity financings are being used to continue to fund the phase 3 trials of sozinibercept.

Sozinibercept is currently being studied in two registrational Phase 3 trials, ShORe and COAST, that plan to enrol nearly 2,000 patients with wet AMD. Throughout the year we expanded our management team in the United States with the addition of a Chief Financial Officer, several key hires in manufacturing, quality and supply chain, and lastly strengthened our presence with investigators and clinical trial sites through the addition of Medical Science Liaisons to our team.

The results from the Phase 2b study of sozinibercept were published in a peer-reviewed journal and throughout the year we continued to educate retina specialists and

ophthalmologists about our ongoing Phase 3 clinical studies and the complimentary mechanism of sozinibercept to be used in combination with standard of care for wet AMD. Our presence at medical conferences and inclusion in several published articles over the last year further increased awareness of sozinibercept and its potential to treat wet AMD patients.

In June 2023 we added Anshul Thakral, an experienced biotech executive with deep clinical trial experience, to our Board of Directors. Mr. Thakral replaced Michael Sistenich, who had served on the Board of Opthea for over seven years. Mr. Sistenich was instrumental in the growth of Opthea, and we wish to thank him for his service and numerous contributions over the years.

We believe the global pandemic had an impact on our original timeline for completion of the phase 3 studies. Based on historical and current trends we anticipate completing enrolment in COAST in the first quarter of calendar year 2024 and in ShORe in the second quarter of calendar year 2024. Once enrolment is complete, patients will be treated for 52 weeks, with topline data expected to be reported once all patients have completed the 52-week dosing period and the data verified and analyzed.

On behalf of the board and management we would like to thank our shareholders for their support and encouragement. We look to the future with enthusiasm and a single-minded dedication to the objective of delivering high value, both to patients and families of those with disorders of the eye and to our shareholders.

Sincerely

**Jeremy Levin**  
Board Chairman  
Opthea Limited



“Our goal is to roll back the terrible loss of sight for millions around the world by fundamentally innovating treatments for AMD.”

Jeremy Levin, Chairman



## CEO'S LETTER

Dear Shareholders,

Over the last year, Opthea has remained steadfast in our conviction to advance sozinibercept, a VEGF-C/D “trap” inhibitor, through Phase 3 clinical trials for wet AMD. Our conviction is based on the limitations of currently available treatments for this highly debilitating and progressive disease of the retina, and the understanding that many patients continue to experience insufficient visual acuity gains to resume routine daily activities despite receiving ongoing and regular standard of care treatment. Opthea’s approach to target VEGF-C and VEGF-D, and to use sozinibercept in combination with anti-VEGF-A therapies to more effectively block disease pathways, is designed to deliver superior vision outcomes over those that can be achieved with currently available treatments that are administered alone as monotherapy.

With this in mind, Opthea has continued to focus on the execution of our Phase 3 pivotal registration studies of sozinibercept for the treatment of wet AMD. With the commitment of patients around the world and the dedication of hundreds of clinical trial sites and investigators who are involved in our study, we were pleased to recently report that our Phase 3 trials COAST and ShORe are approximately 75% enrolled. We continue to invest resources, time and effort to completing patient enrolment which, as an important milestone for the company, will see our focus pivot to the primary ‘topline’ analysis of the outcomes of the trials, which is expected after all patients complete the 52-week dosing period.

With the completion of the non-dilutive Development Funding Agreement (DFA) of US\$120 million with Carlyle/ Abingworth in August 2022 and the equity funding of US\$90 million completed in parallel, we have expanded our management team and oversight of the ShORe and COAST studies. In completing this funding from Carlyle and Abingworth, we have also gained access to the team at Launch Therapeutics, who have added resources to assist in these efforts and prepare for the analysis of results.

We continue to increase our presence with retinal specialists and healthcare professionals through presentations and participation at select medical conferences worldwide. The results of Opthea’s Phase 2b study of sozinibercept (OPT-302) in wet AMD were published in a peer-reviewed journal in 2023 and clinical data from previously completed trials of sozinibercept were presented on the podium at the Ophthalmology Innovation Summit and American Society of Retinal Specialists (ASRS) in August 2023. Recognising the importance of continued engagement with the retinal clinical community and our clinical trial sites, we have added Medical Science Liaisons and additional clinical and medical affairs team members in the United States to expand the understanding of our Phase 3 program and potential of sozinibercept to improve vision outcomes for patients. Our efforts have seen an increase in the number of key opinion leaders publishing and presenting on the importance of sozinibercept as a late stage clinical asset with the potential to provide better vision benefit for their patients.

Our focus for the next twelve months will be to complete patient enrollment into both ShORe and COAST Phase 3 trials and to prepare for primary analysis and topline data readout. We will continue to monitor our sites and patients as they advance through our Phase 3 program and to continue critical elements of manufacturing and commercial readiness.

Our achievements this year would not be possible without the efforts of all our employees and the support and guidance of our Board, the patience from our shareholders and the dedication of many investigators and patients who are participating in our Phase 3 program.

Thank you for your support.

**Megan Baldwin PhD**  
CEO & Managing Director  
Opthea Limited

# FORWARD-LOOKING STATEMENTS

Certain statements in this report may contain forward-looking statements within the meaning of the US Private Securities Litigation Reform Act of 1995. Any statement describing Opthea's goals, expectations, estimates, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement. Forward-looking statements in this report include statements regarding the therapeutic and commercial potential and size of estimated market opportunity of the Company's product in development, the viability of future opportunities, future market supply and demand, the expected receipt of payments (including the additional potential increase of US\$50 million of funding under the Development Funding Agreement ("DFA")) and the timing of such payments, the expected cash runway, the expected timing of completion of patient enrollment under the clinical trials and timing of top-line data, the financial condition, results of operations and businesses of Opthea, certain plans, objectives and strategies of the management of Opthea, including with respect to the current and planned clinical trials of its product candidate, Opthea's goal of building out a substantial presence in the United States and the future performance of Opthea. Forward-looking statements, opinions and estimates provided in this report are based on assumptions and contingencies which are subject to change without notice, as are statements about market and industry trends, which are based on interpretations of current conditions.

Forward-looking statements, including projections, guidance on the future financial position of the Company are provided as a general guide only and should not be relied upon as an indication or guarantee of future performance. They involve known and unknown risks and uncertainties and other factors, many of which are beyond the control of Opthea and its directors and management and may involve significant elements of subjective judgment and assumptions as to future events that may or may not be correct. These statements may be affected by a range of variables which could cause actual results or trends to differ materially, including but not limited to the risks described more fully in the section titled "Risk Factors" included at the end of this report, in Opthea's Annual Report on Form 20-F

filed with the SEC on October 28, 2022 and in the Company's investor presentation on Form 6-K filed with the SEC on August 24, 2023 under "Key Risks", including risks associated with: the availability of funding, the receipt of funding under the DFA (including the additional potential increase of US\$50 million of funding under the DFA), future capital requirements, the development, testing, production, marketing and sale of drug treatments, regulatory risk and potential loss of regulatory approvals, ongoing clinical studies to demonstrate OPT-302 safety, tolerability and therapeutic efficacy, additional analysis of data from Opthea's Phase 3 clinical trials once unmasked, timing of completion of Phase 3 clinical trial patient enrollment and CRO and labor costs, intellectual property protections, and other factors that are of a general nature which may affect the future operating and financial performance of the Company. No representation, warranty or assurance (express or implied) is given or made in relation to any forward-looking statement by any person (including the Company and Opthea Related Persons). In particular, no representation, warranty or assurance (express or implied) is given that the occurrence of the events expressed or implied in any forward-looking statements in this report will actually occur. Actual results, performance or achievement may vary materially from any projections and forward-looking statements and the assumptions on which those statements are based. The forward-looking statements in this report speak only as of the date of this report. Subject to any continuing obligations under applicable law or any relevant ASX listing rules, the Company and Opthea Related Persons disclaim any obligation or undertaking to provide any updates or revisions to any forward-looking statements in this report to reflect any change in expectations in relation to any forward-looking statements or any change in events, conditions or circumstances on which any such statement is based. Nothing in this report will create an implication that there has been no change in the affairs of Opthea since the date of this report.

# ENVIRONMENTAL, SOCIAL AND GOVERNANCE

## What sustainability means to Opthea

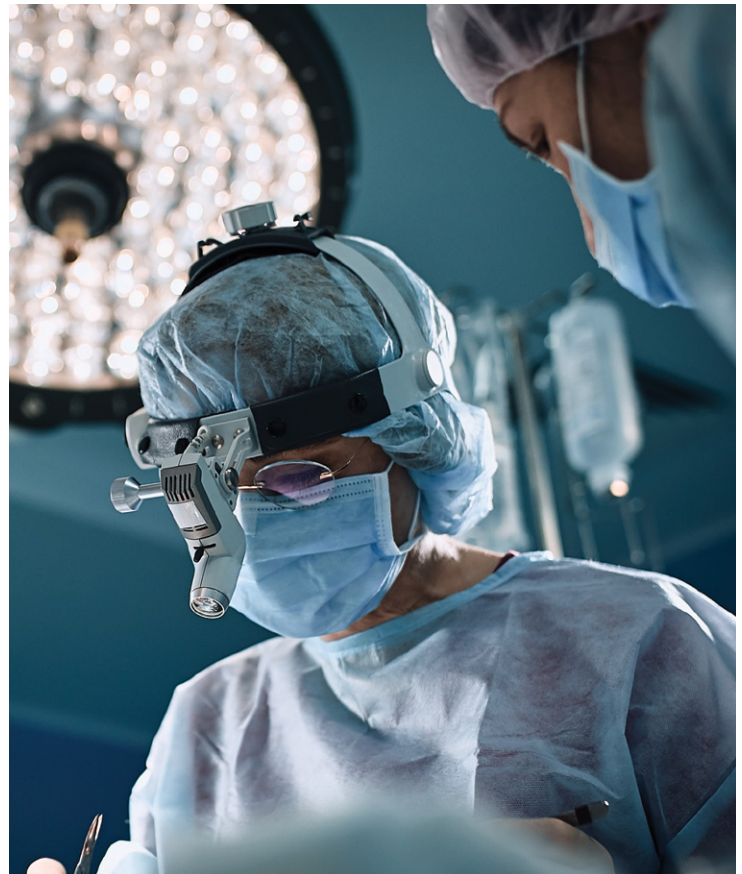
As a biotechnology innovator, Opthea recognizes the opportunity for shared value creation in developing a strong Environmental, Social and Governance or “ESG” framework. Our strategy is designed to align positive outcomes for both the organization and the betterment of public health. We do this by integrating ESG considerations across all facets of our operations. To us, the essence of sustainability is captured in our mission statement:

“Our mission is to expeditiously develop our innovative therapies to improve vision and enhance public health for better quality of life.”

Integrating ESG allows us to align our operations with long-term sustainability goals, working to build responsible research and development practices, ethical supply chains, and positive social impacts. We believe that enhancing our ESG policies improves our resilience and contributes to the overall well-being of individuals and the planet.

This is our second inclusion of ESG into our reporting. As our business matures, we intend to continue reporting against key issues and metrics defined by the developing International Sustainability Standards Board (ISSB) guidelines. The goal of this reporting is to offer stakeholders concise and reliable information regarding Opthea’s strategic focus and future orientation. Healthcare and innovation, cornerstones of Opthea’s business practice, are two critical elements of sustainable development. Considering this, Opthea seeks to offer returns with positive impact to our investors and the global community.

With an aging global population, the prevalence of wet AMD, a debilitating eye disease that can cause severe vision loss, is increasing and placing a significant burden on individuals and healthcare systems.



Wet AMD affects over 3.5 million people in the US and Europe, negatively impacting the quality of life for those affected. Addressing this issue is crucial as it not only restores visual function and independence for individuals but also reduces the socioeconomic impact of vision impairment. In addition, Opthea’s research and development contributes to advancements in the field of ophthalmology and eye care. Our innovative approaches and scientific discoveries can lead to a deeper understanding of the underlying mechanisms of eye diseases and catalyze further research and breakthroughs in the broader scientific community.



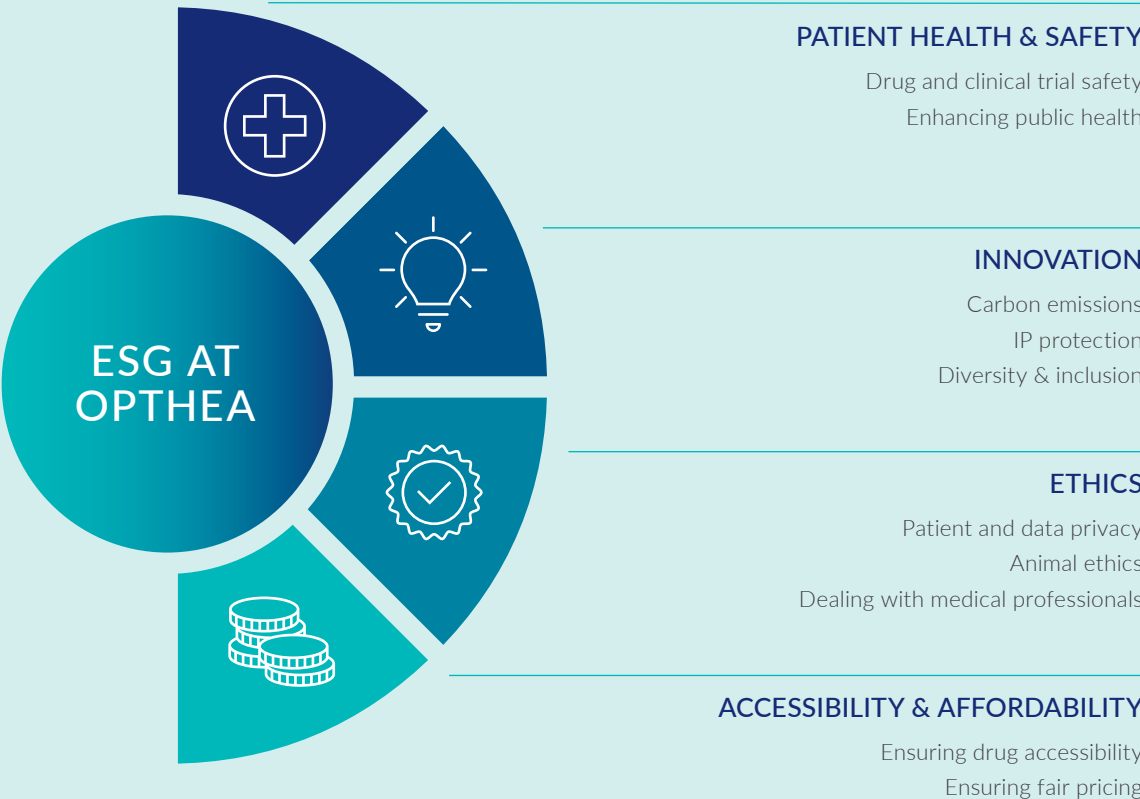
### Opthea’s 4 pillars

Last year Opthea completed a materiality assessment and stakeholder analysis to gain a comprehensive understanding of our key ESG focus areas and to prioritize our actions effectively. We plan to regularly perform assessments in a continuous effort to address those issues most important to both Opthea and our stakeholders.

This assessment helps us focus our efforts on areas where we can have the greatest positive impact and to identify and mitigate risks. Understanding the issues most important to our stakeholders allows us to better

meet expectations and develop effective and targeted strategies. The analysis assists in aligning our operations, products, and corporate practices with the expectations of stakeholders, with the ultimate goal of enhancing our overall sustainability performance and long-term success.

Opthea has identified four ESG focus pillars, with key issues under each. Opthea takes the approach of double materiality, meaning we consider both issues that affect Opthea, but also how our organization can impact society and the environment.





## Pillar 1: Patient health and safety

### *Drug and clinical trial safety*

Drug safety is of utmost importance at Opthea. We promote the well-being and protection of patients by minimizing the risks and potential harm associated with medications. We prioritize patient safety above all else, conducting rigorous research, development, and testing of our development products, and monitor the well-being of our patients and the safety profile of our product. Once commercially available, Opthea plans to disclose quantitative measures of drug safety to offer transparency across our drug safety record.

We have protocols in place to monitor clinical trial safety and have adopted comprehensive guidelines for overseeing the drug supply chain. These range from clarity over labor practices, to environmental tracking, and serve as a measure against counterfeiting. Monitoring the safety and efficacy of our drugs is one of the primary methods by which Opthea strives to enhance public health. The entire manufacturing process is closely tracked with unique batch numbers, tamper-resistant seals, temperature logging data, ID testing, and quality control procedures. These procedures cover our operations from raw material procurement to manufacturing, packaging and shipment, labeling, and distribution.

## *Enhancing public health*

Enhancing public health sits firmly within Opthea's mission and philosophy. The sustainability of our business is mutually dependent on our ability to deliver positive health outcomes to our patients. Our ambition is to contribute substantially to improving vision throughout society, and we work toward this every day through our research and development efforts.

## Pillar 2: Innovation

### *Carbon emissions*

Opthea recognizes the urgency to reduce greenhouse gas emissions to avoid the worsening effects of climate change. This year we calculated our Scope 1 and 2 emissions using the Greenhouse Gas Protocol guidelines. Our FY23 CO<sub>2</sub>-e total was 4.24 tonnes, principally from our scope 2 purchased electricity usage. This is a comparatively small total, and when possible, we will endeavor to reduce our footprint by purchasing renewable electricity. In the future, we hope to calculate our scope 3 indirect emissions (upstream and downstream) to further understand and reduce our emissions profile. We currently purchase offsets through our carrier when flights are essential for business travel.

Our ambition is to contribute substantially to improving vision throughout society, and we work toward this every day through our research and development efforts.

Opthea prioritizes waste reduction through partnerships with sustainable vendors for our medical products, promoting the decoupling of medical products from plastic waste. In our Melbourne office, we adopt a collective approach to managing office waste. As we prepare for our products that may enter the market, we are developing a waste stream procedure to address key waste sources, namely plastic needles, glass vials, and associated packaging.

#### ***IP protection***

The development of an innovative therapy to improve patient vision underpins Opthea's value. Considering this, we understand that IP protection is a key issue. To protect our intellectual property, Opthea engages professional patent attorneys to provide oversight of our patent portfolio and implement actions to protect it. Additionally, Opthea recognizes the importance of fair and ethical competitive practices in fostering a healthy business environment. To uphold these principles, the company maintains robust corporate governance measures in place to address competitive behavior.

Opthea fosters a culture of innovation within the company by encouraging creativity, promoting collaboration, and providing resources to support experimentation. Through these efforts, Opthea inspires and contributes to the development of our novel therapies and to the future of biomedicine.

#### ***Diversity and inclusion***

Through diversity, Opthea can tap into a wide range of perspectives, experiences, and talents, leading to more creative problem-solving and better outcomes. Inclusion promotes an environment where every individual is valued and respected, fostering an environment where everyone can contribute their best.

During the three years ended June 30, 2023, 38% of the directors and 55% of employees were female. As of June 30, 2023, we had 24 full-time employees, eight of whom had an MD or Ph.D. degree. None of our employees are represented by collective bargaining agreements. We believe that our management maintains good relations with our employees. As of June 30, 2023, our employees were based in Australia (8) and the United States (16), with 17 employees in our research and development and commercialization department and seven employees in our general and administrative department.

Opthea's ambition is to create a diverse and inclusive workforce that reflects the global communities it serves. We believe that everyone at Opthea has a voice, and that this fosters an open, respectful, and collaborative culture.

### Pillar 3: Ethics

#### *Patient and data privacy*

Opthea is working to safeguard patient information and privacy by following General Data Protection Regulation (“GDPR”) principles and guidelines and utilizing secure systems that de-identify patient information. With an increase in data breaches in various sectors over the past year, having a procedure in place to protect the data privacy of our patients is more important than ever. We recognize the importance of patient privacy and adhere to comprehensive guidelines for protecting and secure handling of personal data. De-identifying patient information by removal or encryption of personally identifiable data in a secure system, is one of our ways to demonstrate that we place data privacy at great importance.

At Opthea, we have also established a Data Monitoring Committee (“DMC”) that follows data protection and privacy rules, as well as data privacy training procedures for all our staff. This demonstrates our commitment to fostering a privacy-conscious workforce.

#### *Animal ethics*

Opthea is committed to conducting research and development in a responsible and ethical manner. We recognize the intrinsic importance and significance of animal welfare and prioritize high ethical standards throughout our supply chain. We minimize animal testing by the “Three Rs” principle, being the reduction, refinement, and replacement of animals in scientific research. Opthea actively seeks alternative methods and technologies to reduce reliance on animal experimentation and replaces animals wherever possible.

We strictly adhere to internationally recognized guidelines and regulations that aim to safeguard the welfare and well-being of animals involved in our studies, placing their care and humane treatment as a top priority.

#### *Dealing with medical professionals*

Opthea adheres to the highest standards of integrity, transparency, and professionalism when dealing with medical professionals. We work to ensure compliance with applicable laws and regulations, avoid conflicts of interest whether they be personal or financial, and maintain independence and objectivity in the judgement of medical opinions. This is done through transparent relationships designed to prevent conflicts of interest, through fair trading and dealing, and through our anti-bribery policies. Details of these can be found in our Code of Conduct statement.



### Pillar 4: Accessibility, affordability, and fair pricing

Opthea believes that our mission to enhance public health for better quality of life is one that should be shared with the entire community. We are committed to making medical products and treatments accessible to as many individuals as possible. When bringing our products to market, we are working to obtain coverage under the US benefits schedule, meaning a co-payment price to improve the accessibility of the drug to those who need it. Opthea is reaching out to insurers to drive for this outcome, as well as to gauge price expectations.

We expect our product to be priced at fair market value for novel products. In the US and Japan in particular, we expect that there will be a co-payment of which the vast majority of patients have supplemental insurance coverage. Many of the remaining developed nations have social medical coverage and we expect that patients will also have affordable access to this medicine. We plan to engage the requisite marketing, medical affairs, and sales personnel to promote the awareness of the affordability, efficacy, and safety of our products among our health care providers and patients.

Affordable medicines contribute to the long-term sustainability of healthcare systems, and ultimately benefit public health by reducing the burden on patients and insurance providers. Our commitment to fairly priced medical treatment is part of our dedication to patient-centered care.

## Our contribution to the Sustainable Development Goals

The Sustainable Development Goals (SDGs) are a set of 17 global objectives established by the United Nations in 2015 to address socio-economic and environmental challenges. They aim to provide a common framework against which global efforts can be directed. Opthea has identified the goals and relevant sub-goals to which we expect our operations and mission contribute.

While Opthea's research is expected to contribute most clearly to Good Health and Well-being (SDG 3), it is important to consider the breadth of impact that our organization can have across multiple goals.

**3** GOOD HEALTH AND WELL-BEING



### SDG 3 Good health and wellbeing

#### 3.8 Achieve universal health coverage

Opthea is driving for access to quality essential healthcare services, access to safe and affordable medicines.

**9** INDUSTRY, INNOVATION AND INFRASTRUCTURE



### SDG 9 Industry, innovation and infrastructure

#### 9.5 Enhance scientific research, upgrade technological capabilities of industrial sectors, and encourage innovation.

Scientific research is at the heart of what Opthea does, as is striving for medical innovation.

**10** REDUCED INEQUALITIES



### SDG 10 Reduced inequalities

#### 10.2 By 2030, empower and promote the social, economic, and political inclusion of all, irrespective of age, sex, disability, race, ethnicity, origin, religion, or economic or other status.

Opthea promotes diversity and equality throughout our hiring and employment policies. We also see ourselves contributing towards a reduction in long term healthcare inequality.

**12** RESPONSIBLE CONSUMPTION AND PRODUCTION



### SDG 12 Responsible consumption and production

#### 12.5 By 2030, substantially reduce waste generation through prevention, reduction, recycling and reuse.

We work to minimise plastic consumption wherever possible and will continue to do so as our products come to market.

**13** CLIMATE ACTION



### SDG 13 Climate action

#### 13.3 Improve education, awareness-raising and human and institutional capacity on climate change mitigation, adaptation, impact reduction and early warning.

As we expand our emissions profile to scope 3, we intend to improve understanding of CO<sub>2</sub> hotspots, and mitigate where possible.

# Directors' Report

The board of directors of Opthea Limited submits its report for the year ended June 30, 2023 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:

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Jeremy Levin, Non-Executive Director and Chairman

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Megan Baldwin, Managing Director and Chief Executive Officer

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Susan Orr, Non-Executive Director

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Michael Sistenich, Non-Executive Director (resigned June 7, 2023)

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Lawrence Gozlan, Non-Executive Director

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Daniel Spiegelman, Non-Executive Director

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Julia Haller, Non-Executive Director

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Quinton Oswald, Non-Executive Director

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Anshul Thakral, Non-Executive Director (appointed June 7, 2023)

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

## Company Secretary

### Karen Adams

BBus, CPA GAICD, FGIA FCG

Karen Adams, a fellow of the Governance Institute of Company Secretaries, was appointed as Vice President Finance and Company Secretary on June 15, 2021.

### Jeremy Levin

PhD, MB BChir  
Non-Executive Director and Chairman

Dr. Jeremy Levin has served as the Chairperson of the board of directors since October 2020. Since 2015 Jeremy has served as the Chief Executive Officer of Ovid Therapeutics Inc., and since 2014, as Chairperson of the board of directors, of Ovid. From May 2012 to October 2013, Dr. Levin served as the President and Chief Executive Officer of Teva Pharmaceutical Industries Ltd., a publicly held pharmaceutical company. From September 2007 to December 2012, Dr. Levin held several roles at Bristol Myers Squibb Company, a publicly held pharmaceutical company, ultimately serving as the Senior Vice President of Strategy, Alliances and Transactions. Dr. Levin also served as a member of the executive committee at Bristol Myers Squibb Company. Dr. Levin earned a BA in Zoology, a MA in Cell Biology and a PhD in Chromatin Structure, all from University of Oxford, and a MB BChir from the University of Cambridge.

### Megan Baldwin

BSc (Hons), PhD  
Managing Director and Chief Executive Officer

Dr. Megan Baldwin was appointed CEO and Managing Director in February 2014. Dr. Baldwin brings over 20 years' of experience focusing 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, formerly a 100% owned subsidiary of Opthea, developing sozinibercept for the treatment of wet AMD. Prior to joining Opthea, she was employed at Genentech Inc. (now a member of the Roche Group), a 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, a Director of Ausbiotech.

### Michael Sistenich

MSc  
Non-Executive Director

Michael Sistenich was appointed Non-Executive Director of Opthea in November 2015 and resigned June 7, 2023, and was Chairman of the Remuneration Committee during his term. 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 \$17.4 million 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.

### Lawrence Gozlan

BSc (Hons)  
Non-Executive Director

Lawrence Gozlan was appointed as a director on July 24, 2020 and is Chairman of the Nominations Committee. Mr. Gozlan, a biotechnology investor and advisor, is the Life Sciences Investment Manager at Jagen Pty Ltd, an international private investment organization. Mr. Gozlan is also the Chief Investment Officer and Founder of Scientia Capital, a specialized global investment fund focused exclusively on life sciences. Scientia was founded to provide high level expertise and to manage investments for high-net-worth individuals, family offices and institutional investors wanting exposure to the life sciences industry.

Prior to this, Mr. Gozlan was responsible for the largest biotechnology investment portfolio in Australia as the institutional biotechnology analyst at QIC (“the Queensland Investment Corporation”), an investment fund with over \$60 billion under management. He previously worked as the senior biotechnology analyst in the equities team at Foster Stockbroking, and gained senior corporate finance experience advising life science companies at Deloitte. Mr. Gozlan holds a Bachelor of Science with Honors in microbiology and immunology from the University of Melbourne.

### **Daniel Spiegelman**

**BA, MBA**  
**Non-Executive Director**

Daniel Spiegelman has served as a member of the board of directors since September 2020 and is Chairman of the Audit and Risk Committee. From May 2012 to January 2020, Mr. Spiegelman served as Executive Vice President, Chief Financial Officer of BioMarin Pharmaceutical Inc., a biotechnology company. From May 2009 to May 2012, Mr. Spiegelman served as a consultant to provide strategic financial management support to a portfolio of public and private life science companies. Mr. Spiegelman has also served as a member of the board of directors of Myriad Genetics, a molecular diagnostic company since May 2020, a Director of Jiya Acquisitions Corp since November 2020 and a Director of Spruce Bioscience since September 2020. Mr. Spiegelman earned a BA from Stanford University and an MBA from the Stanford Graduate School of Business.

### **Dr. Julia Haller**

**MD, BA**  
**Non-Executive Director**

Dr. Julia Haller was appointed Non-Executive Director of Opthea in June 2021. Since 2007, Dr. Haller has served as Ophthalmologist-in-Chief and William Tasman, ME Endowed Chair at Wills Eye Hospital in Philadelphia. She is Professor and Chair of the Department of Ophthalmology at the Sidney Kimmel Medical College at Thomas Jefferson University as well as a Director of Bristol Myers Squibb and Outlook Therapeutics. She is a member of the National Academy of Medicine, the Chair of the College of Physicians of Philadelphia, Chair of the

Heed Ophthalmic Society, past president of the Women in Medicine Legacy Foundation, and serves on several prestigious boards including the board of the John Hopkins Medical and Surgical Association, the Association of University Professors of Ophthalmology, and the Society of Heed Fellows. Dr. Haller received a BA from Princeton University, graduating magna cum laude, and completed her medical training at Harvard Medical School.

### **Dr. Susan Orr**

**OD**  
**Non-Executive Director**

Susan Orr was appointed Non-Executive Director of Opthea in April 2022. Dr. Orr is an experienced medical and business leader with specialization in identifying, developing and commercializing ophthalmic therapeutic product candidates. Dr. Orr currently serves as the Chief Medical Officer at Claris Biotherapeutics and is a member of the Retina Global Board of Directors. Before Claris, Dr. Orr was the Chief Executive Officer at Notal Vision subsequent to joining the company as Chief Medical Officer. Dr. Orr has spent more than 30 years in the field of ophthalmology that also includes ten years in private optometric practice and leadership roles at Alcon and Janssen spanning international development, global new product strategy, and business development and licensing. Dr. Orr participated in multiple acquisitions including Durezol® and Beovu® (brolocizumab) and has been a Managing Partner at Fovenedeye Consulting since 2016.

### **Quinton Oswald**

**Non-Executive Director**

Quinton Oswald was appointed Non-Executive Director of Opthea in April 2022. Mr. Oswald brings over 25 years of international general management experience, including onsite assignments in the US, Europe and South Africa. Most recently, he was the CEO of Notal Vision, a commercial-stage ophthalmic home monitoring services provider with a focus on both wet and dry AMD. Prior to Notal Vision, he served as the CEO of Neurotech and, prior to that, as the CEO of SARcode Bioscience, where he was instrumental in the clinical development of lifitegrast ophthalmic solution 5% (Xiidra®) for

the treatment of dry eye disease, and its subsequent sale to Shire, PLC. Previously, he was Vice President and Business Unit Head for Genentech’s tissue growth and repair business. During his tenure at Genentech, Mr. Oswald oversaw the highly successful commercial launch of Lucentis® (ranibizumab) for the treatment of wet AMD. Before Genentech, Mr. Oswald led the North American Ophthalmology business for Novartis, which, in conjunction with QLT, Inc., pioneered Visudyne®.

### **Anshul Thakral**

**BS, MSE, MBA**  
**Non-Executive Director**

Mr. Thakral is Chief Executive Officer and Board Member of Launch Therapeutics, a clinical development company backed by funds managed by global investment firm Carlyle and its life sciences franchise, Abingworth. Mr. Thakral has worked for over 20 years in the pharmaceutical and biotechnology industry and is an experienced executive, management consultant and entrepreneur. Mr. Thakral was previously Chief Commercial Officer and Executive Vice President of Peri and Post-Approval Services at PPD, and prior to that was Global Head of PPD Biotech. Before PPD, Mr. Thakral ran the global life sciences business unit at Gerson Lehrman Group and worked at McKinsey & Company as an associate principal in the health care practice, where he provided strategic advice to global pharmaceutical and biotechnology companies on growth, research and development, business development and commercialization. He currently serves on the boards of TriNetX, Saama Technologies, Orsini Specialty Pharmacy, is an Operating Executive at Carlyle and is a Venture Partner at Abingworth.

Mr. Thakral holds a Master’s degree in Biomedical Engineering from Johns Hopkins University and a Masters Business Administration (MBA) from the Wharton School at the University of Pennsylvania. We believe Mr. Thakral’s extensive experience in the global biotechnology and pharmaceutical industry qualifies him to serve on our board of directors.

## Directors' Report (cont.)

### Directorships of other listed companies

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

Director	Company	Period of directorship
Jeremy Levin	Ovid Therapeutics Inc (NASDAQ)	Since 1997
Megan Baldwin	Invex Therapeutics (ASX)	Since 2020
Lawrence Gozlan	Alterity Therapeutics Limited (ASX)	Since 2011
Daniel Spiegelman	Myriad Genetics (NASDAQ)	Since 2020
	Spruce BioScience (NASDAQ)	Since 2020
Julia Haller	Bristol Myers Squibb (NYSE)	Since 2019
	Outlook Therapeutics (NASDAQ)	Since 2022

### 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/Rights granted under LTIP and NED Plans
Megan Baldwin	3,839,398	4,600,000
Jeremy Levin	-	3,000,000
Michael Sistenich (resigned June 7, 2023)	1,233,097	1,500,000
Lawrence Gozlan	1,877,357	2,000,000
Daniel Spiegelman	-	2,000,000
Julia Haller	-	2,000,000
Susan Orr	-	1,000,000
Quinton Oswald	-	1,000,000
Anshul Thakral (appointed June 7, 2023)	-	-



## Directors' Report (cont.)

### Share options

As of June 30, 2023 and the date of this report, details of Opthea's interests under option are as follows:

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

During the 2018, 2019, 2021, 2022 and 2023 financial years the Company granted 26,955,000 options, rights and ADS options remain available 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	Number of options granted
August 23, 2017	January 1, 2023	Employees under the LTIP	\$0.92	500,000
November 29, 2018	November 29, 2022	Directors under the LTIP and NED plan	\$0.625	6,000,000
April 3, 2019	April 3, 2023	Employees under the LTIP	\$0.608	2,844,000
October 12, 2020	October 11, 2024	Directors under the NED Plan	\$2.16	2,000,000
October 12, 2020	October 11, 2024	Directors under the NED Plan	\$3.24	2,000,000
January 19, 2021	January 18, 2025	Directors under the NED Plan	\$1.56	3,000,000
October 19, 2021	October 18, 2025	Directors under the NED Plan	\$0.948	2,000,000
October 19, 2021	October 18, 2025	Employees under the LTIP	\$0.948	2,000,000
April 21, 2022	April 21, 2026	Directors under the NED Plan	\$0.75	2,000,000
June 6, 2022	June 6, 2032	Employees under the LTIP	\$1.46	800,000
April 21, 2022	April 21, 2026	Directors under the NED Plan	\$0.75	2,000,000
November 16, 2022	November 16, 2032	Directors under the NED Plan	\$0.658	3,500,000
November 16, 2022	November 16, 2032	Directors under the NED Plan	\$0.672	2,000,000
November 16, 2022	November 16, 2032	Directors under the LTIP	\$0.658	3,000,000
December 13, 2022	December 13, 2032	Employees under the LTIP	\$0.644	250,000
				<b>31,894,000</b>

Grant date	Expiry date	Granted to	Exercise price	Number of performance rights
October 19, 2021	October 19, 2031	Director under the LTIP	\$ Nil	1,600,000
November 16, 2022	November 16, 2032	Director under the LTIP	\$ Nil	650,000
November 16, 2022	November 16, 2032	Director under the NED	\$ Nil	650,000
				<b>2,900,000</b>

## Directors' Report (cont.)

Grant date	Expiry date	Granted to	Exercise price	Number of ADS options
January 10, 2022	January 10, 2032	Employees under the LTIP	\$7.51	150,000
March 1, 2022	March 1, 2032	Employees under the LTIP	\$6.01	300,000
April 18, 2022	April 18, 2032	Employees under the LTIP	\$6.09	80,000
May 23, 2022	May 23, 2032	Employees under the LTIP	\$7.12	80,000
June 1, 2022	June 1, 2032	Employees under the LTIP	\$7.45	80,000
June 20, 2022	June 20, 2032	Employees under the LTIP	\$5.52	60,000
July 1, 2022	July 1, 2032	Employees under the LTIP	\$6.35	175,000
October 24, 2022	October 24, 2032	Employees under the LTIP	\$4.85	300,000
October 28, 2022	October 28, 2032	Employees under the LTIP	\$5.17	20,000
January 16, 2023	January 16, 2033	Employees under the LTIP	\$4.93	50,000
February 1, 2023	February 1, 2033	Employees under the LTIP	\$5.24	75,000
February 13, 2023	February 13, 2033	Employees under the LTIP	\$5.15	25,000
April 18, 2023	April 18, 2033	Employees under the LTIP	\$3.54	110,000
				<b>1,505,000</b>

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 commercialize therapies primarily for eye disease. Opthea's lead asset, sozinibercept (OPT-302), is a soluble form of vascular endothelial growth factor receptor-3 "VEGFR-3" in clinical development as a novel therapy for wet age-related macular degeneration (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 2022-2023 included progression of the Company's Phase 3 registrational trials of sozinibercept (OPT-302) for wet AMD through the activation of clinical trial sites in countries globally and continued enrollment of patients into the studies. Opthea also manufactured sozinibercept for use in the Phase 3 clinical trials, conducted activities to support commercialization of the product and expanded its management team in the US to facilitate broader oversight and execution of its Phase 3 program.

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.

## Directors' Report (cont.)

### 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 sozinibercept for wet AMD.

A summary of the results is as follows:

- The major expenditure of the Group has been in relation to Research & Development ("R&D"), in particular costs associated with the Phase 3 clinical trials;
- Total R&D expenditure amounted to US\$122,128,314 (2022: US\$78,654,217). Including personnel costs and other R&D support costs which are included in administrative costs, total expenditure in R&D tax claim amounted to US\$13,623,793 (2022: US\$14,481,116);
- Opthea received an R&D tax incentive payment during the year of US\$6,299,286 (2022: US\$4,972,898); and
- The consolidated net loss of the Group for the year was US\$128,426,262 after an income tax benefit of US\$5,926,350 (2022: loss of US\$92,817,371 after an income tax benefit of US\$6,299,286).

#### Financial position

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

- Consolidated cash balances as of June 30, 2023 amounted to US\$89,188,713 (2022: US\$44,631,293);
- Receivables of US\$6,562,915 (2022: US\$6,556,954) include the Opthea Group's expected refund of R&D tax incentives for the year to June 2023 of US\$5,926,350 (2022: US\$6,299,286);
- The Group has a net current asset surplus of US\$79,643,659 (2021: US\$47,866,741); and
- The net tangible asset backing per share as at June 30, 2023 was (US\$0.01) (2022: US\$0.14); Opthea's share price was A\$0.52 (2022: A\$1.10).

#### Opthea: Company overview

Opthea is committed to the development of new therapies for the treatment of serious eye diseases that affect the back of the eye, or retina, and lead to vision loss.

Opthea's lead candidate Sozinibercept (OPT-302) is a first in class VEGF-C/D inhibitor being developed as a complementary treatment to be used in conjunction with VEGF-A inhibitors for the treatment of wet AMD and other retinal diseases. Sozinibercept has the potential to be combined and positioned as complementary with any anti-VEGF-A therapy for the treatment of wet AMD, a strategy intended to maximize the commercial opportunity for the therapy.

Wet AMD is a progressive, chronic disease of the retina and in developed nations, is the leading cause of visual impairment in people over the age of 50 years. Wet AMD is associated with blood vessel dysfunction and proliferation in the macula, a region of the retina which is needed for sharp, central vision. New blood vessels break through layers of the retinal tissue, leaking fluid, lipids and blood, leading to fibrous scarring and loss of vision. Vision loss associated with wet AMD can be rapid and is generally severe, impacting patient independence and contributing to significant healthcare and economic costs worldwide.

Although the underlying cause and biology of wet AMD is complex, inhibition of vascular endothelial growth factor A, or VEGF-A, has been shown to play an important role in the growth and leakage of vessels associated with the disease, and inhibitors of VEGF-A are now standard of care treatments for wet AMD. The VEGF-A inhibitors ranibizumab (Lucentis®) and aflibercept (Eylea®), approved for the treatment of wet AMD and other retinal indications, together generated worldwide revenues in excess of US\$12 billion in 2022. Such commercial success reflects the widespread use of the VEGF-A inhibitor class of therapies and the importance that physicians and patients alike attribute to the preservation and improvement of visual acuity for quality of life.

## Directors' Report (cont.)

However, despite many patients experiencing gains or stabilization of vision, at least 45% of patients with wet AMD exhibit a sub optimal response to therapies that selectively target VEGF-A. As such, there remains a very large commercial opportunity for novel therapies that address the unmet medical need for patients who have further room for improvement in visual acuity despite regular administration of currently available treatments.

Opthea's lead product candidate sozinibercept is differentiated with a key objective to improve clinical efficacy and the potential to also produce more sustained, durable clinical outcomes for patients. The majority of agents currently in clinical development are seeking to reduce the frequency of patient treatments, rather than provide superior vision gains for those affected by retinal diseases. With a scarcity of combination therapies in development that may offer improved outcomes for retinal disease patients, and with positive Phase 2b data in wet AMD, we believe sozinibercept is a promising drug candidate with large commercial potential as it advances through the final stage of clinical development, Phase 3 pivotal studies.

### Sozinibercept: Opthea's Phase 3 asset for the treatment of wet AMD

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

Current treatments, as well as many agents currently in clinical development for wet AMD and DME, share a common mechanism of action by inhibiting VEGF-A. Sozinibercept has a differentiated mechanism of action by binding and blocking the activity of VEGF-C and VEGF-D, which are also important stimulators of blood vessel growth and vascular leakage and implicated in the progression of retinal diseases. Sozinibercept is a soluble fusion protein consisting of the first three extracellular domains of VEGFR-3 fused to the Fc fragment of human immunoglobulin G1 (IgG1). Sozinibercept binds or "traps" VEGF-C and VEGF-D with high affinity, blocking the activity of both proteins.

Sozinibercept is administered by intravitreal injection into the eye, which is the same route of administration of approved, standard of care treatments for wet AMD. By combining administration of sozinibercept, with a VEGF-A inhibitor through sequential intravitreal injections, broader 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. In addition, inhibition of VEGF-A results in compensatory upregulation of VEGF-C and VEGF-D that may limit the efficacy of selective VEGF-A inhibitors. Sozinibercept blocks this mechanism of resistance to existing therapies which may then result in improved and more durable clinical responses.

### Operational update

Over the past 12 months, Opthea continued to advance its clinical development program investigating sozinibercept as a combination therapy for wet AMD. The majority of the Company's activities were focused on progressing its Phase 3 pivotal program in wet AMD, through continued patient recruitment into the ShORe and COAST clinical trials which are, as of August 2023, approximately 75% enrolled. Throughout the year, Opthea continued to activate clinical trial globally and to manufacture sozinibercept (OPT-302) to current good manufacturing practices, or cGMP standards for use in the clinical trials and for pre-commercial purposes. The Company also conducted activities to support commercialization of the product, included enhancing its presence at clinical ophthalmology conferences and symposia. The Company also participated in several investment events focused on emerging ophthalmology companies. These increased efforts were further facilitated by the growth of Opthea's management team in the US to execute its Phase 3 program and begin pre-commercialization activities.

Sozinibercept was advanced into Phase 3 pivotal trials based on clinical experience to date, which includes three completed clinical trials. At the annual American Society of Retinal Specialists meeting in August 2023 a pooled safety analysis of 399 patients from completed sozinibercept trials was presented. The presentation concluded that the safety data from our completed sozinibercept trials show sozinibercept combination therapy has a safety and tolerability profile comparable to standard of care anti-VEGF-A monotherapy.

## Directors' Report (cont.)

Notably from our previously completed clinical trials, the statistically significant positive outcomes from the Company's 366 patient, randomized, sham controlled Phase 2b clinical trial in treatment naïve wet AMD patients informed the design of the Phase 3 program.

In July 2023, Opthea announced "sozinibercept" as the non-proprietary drug name for OPT-302. The American Medical Association's United States Adopted Names (USAN) Council, in consultation with the World Health Organization's International Non-proprietary Names (INN) Expert Committee, approved and adopted the non-proprietary drug name. Opthea will use the name sozinibercept (formerly OPT-302) in upcoming publications, public statements, and in corporate materials moving forward.

### Opthea's Phase 3 pivotal trials – ShORe and COAST

Opthea's Phase 3 program consists of two concurrent, global, multi centre, randomized, sham controlled studies:

- **ShORe:** Study of Sozinibercept (OPT-302) in combination with Ranibizumab (Study Sozinibercept (OPT-302) 1004); and
- **COAST:** Combination Sozinibercept (OPT-302) with Aflibercept Study (Study Sozinibercept (OPT-302) 1005).

Both ShORe and COAST are currently enrolling treatment naïve patients.

In ShORe, treatment naïve patients with wet AMD are randomized to one of three treatment arms to receive standard of care 0.5 mg ranibizumab every four weeks in combination with either 2.0 mg sozinibercept on a standard every four weeks dosing regimen or 2.0 mg sozinibercept on an extended every eight weeks dosing regimen after three monthly initiating doses, or with sham injections every four weeks.

In COAST, treatment naïve patients with wet AMD are randomized to one of three treatment arms to receive standard of care 2.0 mg aflibercept on its every eight week dosing regimen, after three monthly initiating doses, in combination with either 2.0 mg sozinibercept on a standard every four weeks dosing regimen or 2.0 mg sozinibercept (OPT-302) on an extended every eight weeks dosing regimen after three monthly initiating doses, or with sham injections every four weeks.

Each of the ongoing trials is expected to enroll approximately 990 patients worldwide. The primary endpoint for both trials is mean change in visual acuity from baseline to week 52 for sozinibercept and anti-VEGF-A combination therapy compared to anti-VEGF-A monotherapy, with the Company intending to submit Biologics License and Marketing Authorization Applications with the FDA and EMA respectively following completion of this primary efficacy phase of the trials. Each patient will continue to be treated for a further year to evaluate safety and tolerability over a two-year period.

These two sozinibercept Phase 3 trials build upon and maintain key features for consistency with the Company's positive Phase 2b clinical trial of sozinibercept (OPT-302), while evaluating the administration of sozinibercept combination therapy over a longer treatment period and in a greater number of patients.

In addition, the Phase 3 trials are optimized based on Phase 2b outcomes to maximize probability of success and commercial opportunity. Analysis of the Phase 2b trial demonstrated that sozinibercept (OPT-302) combination therapy increased visual acuity by a further +5.7 letters over ranibizumab monotherapy in wet AMD patients with minimally classic and occult lesions, representing the majority (~80%) of wet AMD patients. Based on this positive data, primary analysis of the primary endpoint of the Phase 3 trials will be first conducted in patients with minimally classic and occult lesions administered sozinibercept (OPT-302) every 4 weeks and every 8 weeks, followed by analysis in the predominantly classic lesions and total patient population.

Opthea expects to complete patient recruitment in the Phase 3 clinical trials of sozinibercept for the treatment of wet AMD in the COAST and ShORe studies in the first and second quarter of calendar year 2024 respectively. The primary outcome of the trials is expected to be reported as topline data when all patients complete the 52-week treatment period for the primary analysis. If the topline results at the completion of the primary efficacy phase are favorable, Opthea expects to file for marketing approval for sozinibercept for the treatment of wet AMD in the United States, European Union and other territories.

## Directors' Report (cont.)

### Corporate update

In August 2022, Opthea was pleased to announce a non-dilutive financing transaction for up to US\$170 million from Carlyle and its life sciences franchise Abingworth, working with their recently formed development company Launch Therapeutics ("Launch Tx"). The non-dilutive financing consists of a US\$120 million commitment and an option to increase funding by a further US\$50 million. The Company has recently been notified that a co-investor of Carlyle and Abingworth intends to increase funding by US\$50 million, which is subject to the co-investor's final due diligence and receipt of regulatory and tax approvals, appropriate documentation and compliance with closing conditions. There can be no assurance that the due diligence will be completed to the satisfaction of the co-investor of Carlyle and Abingworth, that the closing terms and conditions will be satisfied or that we will ultimately receive the additional US\$50 million. If sozinibercept is approved in a major market, Carlyle and Abingworth will be eligible to receive seven fixed success payments over six years, and variable success payments of 7% on annual net sales, which terminate after reaching four times the funded amount.

Concurrent with this non-dilutive financing, Opthea also announced the close of a US\$90 million equity financing which was well supported by existing and new institutional investors, including large global and US-based funds. The private placements consisted of two tranches. The first tranche for A\$60.7 million (US\$41.9 million) was funded on August 24, 2022. Opthea closed the second tranche, for US\$47.5 million, or 59 million shares in September 2022.

In August 2023 Opthea also announced a non-underwritten institutional placement ("Placement") and accelerated non-renounceable entitlement offering of A\$90 million (approximately US\$58 million).

These financing arrangements strengthen Opthea's strategic position to maximize the value of Sozinibercept and will be used to continue advancing the clinical development of sozinibercept for the treatment of wet AMD, including to progress the Phase 3 clinical program and for general corporate purposes. Opthea's successful capital raisings further validate our commitment to bring sozinibercept (OPT-302) to wet AMD patients, a disease for which there remains significant unmet medical need despite the availability of therapies that selectively target VEGF-A.

Opthea believes that its existing cash and cash equivalents as of June 30, 2023, as well as net proceeds from the 2023 Equity Offering, – and the incremental US\$50 million under the funding agreement as described above is received, and the remaining \$35 million under the Funding Agreement which is expected to be received by December 31, 2023, if received, will enable us to fund our operating and research and development expenses into the third calendar quarter of 2024. If patient enrollment continues to be delayed in the future, or if any additional factors cause the Phase 3 clinical trials to be further delayed or more costly, then Opthea will need to obtain additional financing earlier than the third quarter of calendar year 2024. However, Opthea will need to raise additional funds to complete the efficacy and safety phase of both studies and to report top-line data.

The amounts and timing of Opthea's expenditures will depend upon and have been impacted in the past, and may continue to be impacted by, numerous factors, including the results of its research and development efforts, the timing and success of ongoing clinical trials or clinical trials that Opthea may commence in the future, the rate of patient recruitment into the trials, the timing of regulatory submissions, the performance and cost efficiency of third parties that assist Opthea with clinical development, including clinical research organizations ("CROs"), and macroeconomic challenges. Opthea has in the past incurred significantly increased costs in connection with the activities conducted by third party CROs and other service providers to prepare for and progress our Phase 3 clinical trials, and may continue to incur higher than expected costs for such activities in the future. Opthea has based its beliefs and expectations stated above on assumptions that may prove to be wrong. Opthea may also experience future delays in its clinical development or commercialization of sozinibercept for any indication, including due to the factors and conditions set forth above or other factors that Opthea cannot presently anticipate, and may use its available capital resources sooner than Opthea currently expects. Opthea will require additional funding to complete its Phase 3 clinical trials in wet AMD. In addition, Opthea may require additional external funding to meet the minimum cash condition under the non-dilutive financing agreement, including prior to the expected readout of top-line results for Opthea's Phase 3 clinical trials. See the "Risk Factors" section included at the end of this report.

### Significant changes in the state of affairs

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

## Directors' Report (cont.)

### Future developments

Opthea's key objective over the next 12 months is to complete enrollment in the ShORe and COAST Phase 3 clinical trials by continuing patient recruitment into the trials globally and to prepare for topline data readout from the trials, expected when all patients complete the 52-week treatment period.

To achieve this objective, Opthea will continue to engage with clinical trial sites, investigators and the clinical ophthalmology community and focus on robust trial execution.

Over the following 12 months, we will also continue to raise the awareness of the commercial potential inherent in sozinibercept (OPT-302) for the treatment of serious retinal diseases. Opthea will also continue to maintain its presence at international investment and clinical ophthalmology conferences and symposia, progress cGMP manufacturing activities of sozinibercept (OPT-302) to support future commercial efforts and continue pre-commercial activities to position sozinibercept (OPT-302) as a promising therapeutic for the treatment of wet AMD.

### Significant events after balance date

On August 24, 2023, Opthea announced a A\$80 million capital raise consisting via a A\$10 million private placement ("Placement") and a A\$70 million Accelerated Non-Renounceable Entitlement Offer ("ANREO"). On August 28, 2023, Opthea announced an increase in the private placement by a further A\$10 million to increase the overall raise to A\$90 million. The proceeds from the Placement and Entitlement will be used to continue advancing the clinical development of OPT-302 for the treatment of wet Age-related Macular Degeneration (wet AMD) including to progress the Company's Phase 3 clinical trials and for general corporate purposes.

The Equity Financing of A\$90 million (approximately US\$58 million) consists of two closings, of which the first closing of A\$73 million (US\$47 million) consisting of a placement offering and an acceleration portion of an Accelerated Non-Renounceable Entitlement Offer ("ANREO") occurred on September 1, 2023. The second closing of A\$17 million (US\$11 million), representing the remaining institutional and retail portion of the ANREO, occurred on September 20, 2023. The shares were issued and cash received on September 20, 2023.

Subsequent to June 30, 2023, the Group was notified that a new co-investor of Carlyle and Abingworth intends to participate in a funding under the DFA of US\$50 million to increase total DFA funding from US\$120 million to US\$170 million, which is subject to the co-investor's final due diligence and receipt of regulatory and tax approvals, appropriate documentation and compliance with closing conditions. Upon completion of the final due diligence, receipt of regulatory and tax approvals, execution of the appropriate documentation and satisfaction of the closing conditions, the Group expects to receive the additional US\$50 million. While the Group anticipates that the due diligence will be completed to the satisfaction of the co-investor, the necessary approvals will be obtained, the appropriate documentation will be executed and that all closing conditions will be satisfied, there is no assurance that the Group will ultimately receive the additional US\$50 million. If the additional US\$50 million is not received by June 30, 2024, the Group will need to raise additional funds or reduce expenditures to continue as a going concern.

On August 28, 2023 Mr Lawrence Gozlan, a director of the Company, and the Company have entered into a Consultancy Agreement of up to US\$300,000 in respect of the provision of services associated with managing, overseeing and coordinating the conduct and implementation of the Capital Raising. The consultancy agreement is effective for the financial year June 30, 2024. In the opinion of the Directors, these duties are outside the scope of the ordinary duties of a Director.

Besides the above, there are no other significant events after June 30, 2023, to report.

### Environmental regulations

The Company is not subject to significant environmental regulations.

### Indemnification and insurance

During the financial year ended June 30, 2023, 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.

## Directors' Report (cont.)

The Company has insured its directors, the company secretary and executive officers for the financial year ended June 30, 2023. 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.

	Directors' meetings	Meetings of committees			
		Audit & risk	Nomination	Clinical	Remuneration
Number of meetings held	5	6	2	2	4
<b>Number of meetings attended:</b>					
Jeremy Levin	5	6			3
Michael Sistenich (resigned June 7, 2023)	5	6	2		4
Lawrence Gozlan	5	6	2		4
Daniel Spiegelman	5	6	2		
Julia Haller	5			2	4
Anshul Thakral (appointed June 7, 2023)	5	6	1	2	3
Susan Orr	5			2	
Quinton Oswald	5			2	
Megan Baldwin	5	6	1	2	4

### 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	Clinical	Remuneration
Daniel Spiegelman (Chairman)	Lawrence Gozlan (Chairman)	Susan Orr (Chair)	Michael Sistenich (Chairman) (resigned June 7, 2023)
Michael Sistenich (resigned June 7, 2023)	Michael Sistenich (resigned June 7, 2023)	Quinton Oswald	Lawrence Gozlan
Lawrence Gozlan	Daniel Spiegelman	Julia Haller	Julia Haller
Quinton Oswald (July 1, 2023)	Quinton Oswald (June 7, 2023)	Megan Baldwin	Quinton Oswald (Chairman) (June 7, 2023)
Susan Orr (July 1, 2023)			

### 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 92 and forms part of the directors' report for the financial year ended June 30, 2023.



## Directors' Report (cont.)

### 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

This remuneration report, which forms part of the directors' report, sets out information about the remuneration of Opthea Limited's Key Management Personnel for the financial year ended June 30, 2023. Following are the major topics covered in this report:

1. Key Management Personnel
2. Remuneration Philosophy
3. Remuneration Committee
4. Diversity
5. Categorization of Key Personnel
6. Remuneration Framework
7. Service Contracts
8. Valuation of Shares
9. Additional Information

### Key management personnel

The remuneration report details the remuneration arrangements for Key Management Personnel ("KMP") who are defined as those people having authority and responsibility for planning, directing, and controlling the major activities of the group, directly or indirectly. The table below outlines the KMP of the group during the financial year ended June 30, 2023. The individuals were KMP for the entire financial year, except where indicated in the table below:

Non-executive directors	
Jeremy Levin	Chairman, Non-executive director
Julia Haller	Non-executive director
Daniel Spiegelman	Non-executive director
Michael Sistenich (resigned June 7, 2023)	Non-executive director
Lawrence Gozlan	Non-executive director
Susan Orr	Non-executive director
Quinton Oswald	Non-executive director
Anshul Thakral (appointed June 7, 2023)	Non-executive director
Executive officers	
Megan Baldwin	Chief Executive Officer and Managing Director
Karen Adams	Vice President Finance and Company Secretary
Timothy Morris (appointed October 24, 2022)	Chief Financial Officer
Judith Robertson	Chief Commercial Officer
Joel Naor (resigned July 15, 2023)	Chief Medical Officer

Except as noted, the named persons held their current position for the whole of the financial year and since the end of the financial year.

## Directors' Report (cont.)

### Remuneration philosophy

The broad remuneration philosophy is to ensure the remuneration package is consistent with current industry best practices & market trends, properly reflects the person's duties and responsibilities and aligns reward with the delivery of performance that is likely to create value for shareholders. In framing its remuneration strategy, the Board is conscious that Opthea only has a small number of employees (~25) so endeavors to keep its remuneration relatively straightforward. Hence, remuneration packages comprise of fixed remuneration, Short-Term Incentives (STI) in cash, and equity based Long-Term Incentives (LTI). Opthea's staff are required to have specialist knowledge and experience allowing them to develop products over the medium to long-term.

Salary and remuneration benchmarking is undertaken by Opthea each year for executive and non-executive positions. Opthea benchmarks fixed and total remuneration against employment positions of comparable specialization, size and responsibility within the industry. Fixed remuneration is supplemented by providing incentives (variable remuneration) to reward superior performance.

Information is obtained from independent surveys to ensure that remuneration is set at market rates having regard to experience and performance and the need to have effective retention strategies for key executives and scientific staff. Formal performance appraisals are also conducted at least annually for all employees.

Opthea's remuneration structure aims to:

- Attract and retain exceptional people to lead and manage the group and to support internal development of executive talent within the group, recognizing that Opthea is operating in a competitive global pharmaceutical industry environment;
- Drive sustainable growth and returns to shareholders, as executives are set both short-term and long-term performance targets which are linked to the core activities necessary to build competitive advantages and shareholder value;
- Motivate and reward superior performance by the executive team whilst aligning performance elements/KPIs to the interests of shareholders; and
- Create a respectful culture based on superior performance and innovation through appropriately structured individual assessments.

### Remuneration Committee

A Remuneration Committee is established to review and make recommendations to the Board on remuneration packages and policies applicable to directors and employees of the Company. In some cases, the Board may exercise discretion to take account of events and circumstances not envisaged.

The *philosophy* of the Remuneration Committee is to focus on driving performance over and above shareholder and market expectations and, in doing so, to directly reward those individuals who contribute to that performance.

The *Committee* consists of a minimum of three members, the majority being independent directors; and an independent chairman.

The broad *objectives* of the Remuneration Committee are:

- to link remuneration to the creation of shareholder value;
- to offer competitive and appropriate remuneration for the business performance delivered; and
- to put into place a remuneration framework that reflects the responsibilities of the executives while being sufficiently competitive to attract and retain high calibre performers.

The *Role and Responsibilities* of the Remuneration Committee are:

- Oversee the remuneration strategy of the Company and recommend or make such changes to the strategy as the Committee may deem to be appropriate.
- Ensure remuneration policies and practices enable the Company to attract, motivate and retain a diverse mix of directors and executives who will create value for shareholders.

## Directors' Report (cont.)

- Fairly and responsibly remunerate directors and executives having regard to their performance, the performance of the Company and the general pay environment.
- Require that the Board determine remuneration of non-executive directors. The Committee may request management or external consultants to provide necessary information upon which the Board may make its determination.
- Ensure remuneration disclosure compliance in the Company's Annual Report.
- At least annually, review and report on the relative proportion of women and men in the workforce at all levels of the Company as per Principle 3 of the ASX Corporate Governance Principles and Recommendations.
- The Committee shall have the right to seek any information it considers necessary to fulfill its duties, which includes the right to obtain appropriate external advice at the Company's expense.

### Diversity

The directors consider annually if the diversity of the Company's personnel is appropriate. During the three years ended June 30, 2023, 33% of the directors, 58% of employees and 77% of senior executives were female.

### Categorization of KMP

The Key Management Personnel are categorized into two categories:

- **Executive Directors** – Involvement in the day-to-day management of the Company or being in the full-time salaried employment of the Company defines the director as Executive. An Executive Director, through his or her privileged position, has an intimate knowledge of the workings of the Company. There can, therefore, be an imbalance in the amount and quality of information regarding the Company's affairs possessed by executive and non-executive directors. Executive Directors carry an added responsibility. They are entrusted with ensuring that the information laid before the board by management is an accurate reflection of their understanding of the affairs of the Company. Executive Directors need to strike a balance between their management of the Company, and their fiduciary duties and concomitant independent state of mind required when serving on the board.
- **Non-Executive Directors** – The Non-Executive Director plays an important role in providing objective judgment independent of management on issues facing the Company. Not being involved in the management of the Company defines the director as non-executive. Non-Executive Directors are independent of management on all issues including strategy, performance, sustainability, resources, transformation, diversity, employment equity, standards of conduct and evaluation of performance. The Non-Executive Directors should meet from time to time without the executive directors to consider the performance and actions of executive management.

### Remuneration framework

Opthea aims to reward its executives with a level and mix of remuneration appropriate to their position, skills, experience and responsibilities, while being market competitive and enabling the Company to retain staff as well as structuring awards which conserve cash reserves. Hence, a defined remuneration framework has been crafted for both Executive and Non-Executive Directors of the Company.

#### Remuneration framework for – Executive Directors

##### *Fixed compensation*

A 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. No external advice has been sought during either 2023 or 2022.

Fixed compensation comprises salary, retirement benefits (superannuation/401k), and other benefits (like health, life insurance, disability, etc.) are reviewed every 12 months by the remuneration committee. Group and individual performance are considered during the annual remuneration review process.

## Directors' Report (cont.)

### *Performance linked compensation*

The remuneration framework also incorporates “at risk” components, which are linked to the performance, through Short-Term and Long-Term Incentives. Performance is assessed against a suite of measures relevant to the success of the group and generating growth and returns for shareholders.

- **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 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 2023 financial year in August 2023. Based on the achievement of operational objectives in the financial year, the remuneration committee has determined there will be US\$354,954 STI bonus paid to KMP for the 2023 financial year (2022: US\$261,456).

- **Long-Term Incentive (LTI):** The objective of the LTI is to reward KMP in a manner that aligns this element of compensation with the creation of shareholder wealth. LTI 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 LTI plan to attract, retain and motivate eligible employees, essential to the continued growth and development of the Company. The LTI was approved by shareholders at the Company's 2014 AGM. The limit of the Company's share capital to be granted under the LTI was increased to 10% at the 2016 EGM.

### **Remuneration framework for – Non-Executive Directors**

The remuneration for Non-Executive Directors is restricted to fees which is determined based on the maximum aggregate fee pool. Non-Executive Directors remuneration is set annually by the Remuneration Committee through a process that uses independent surveys to establish the market rate for Non-Executive Directors' remuneration in equivalent sized companies operating in an equivalent or similar field. The Committee recognizes the need to attract and retain appropriately experienced and qualified Board members and the increasing commitment of time required by each Board member in the current regulatory environment. The fees also reflect the demands which are made on, and the responsibilities of, the Non-Executive Directors, whilst incurring a cost which is acceptable to shareholders.

### *Annual review*

Non-Executive Directors' fees and the aggregate fee pool are reviewed annually by the Remuneration Committee against fees paid to Non-Executive Directors in a group of comparable peer companies within the biotechnology sector and relevant companies in the broader US and ASX-listed market. The Chairman's fees are determined by the Remuneration Committee independently of the fees of Non-Executive Directors based on the same role, again using benchmarking data from comparable companies in the relevant sector. The Board is ultimately responsible for approving any changes to Non-Executive Director fees, upon consideration of recommendations put forward by the Remuneration Committee.

## Directors' Report (cont.)

### Fee policy

Non-Executive Directors' fees consist of base fees and committee fees. The payment of committee fees recognizes the additional time, responsibility and commitment required by Non-Executive Directors who serve on board committees. The Chairman of the Board is a member of all committees but does not receive any committee fees in addition to his base fee.

Non-Executive Directors did not receive bonuses or forms of equity securities, or any performance-related remuneration during the financial year except where stipulated in the Remuneration table. Statutory superannuation contributions are required under the Australian superannuation guarantee legislation to be paid on any fees paid to Australian directors. There are no retirement allowances paid to non-executive directors. The Non-Executive Directors' fees reported below include any statutory superannuation contributions.

### 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. Due to the change in functional currency and presentation currency in the current year, the current and prior year has been restated to US currency with the remaining years remaining in A\$. Refer to Note 3 Change in presentation and functional currencies for more information in regard to the determination of the change.

	2023 US\$	2022 US\$	2021 A\$	2020 A\$	2019 A\$
Revenue including finance income	3,335,902	326,151	440,615	539,514	914,840
Loss before tax	(142,521,085)	(99,116,657)	(50,283,342)	(16,831,966)	(35,547,034)
Tax benefit	5,926,350	6,299,286	4,938,846	5,708,767	14,636,973
Loss after tax	(142,521,085)	(92,817,371)	(45,344,496)	(11,123,199)	(20,910,061)

2022 and 2021 is US\$ with remaining years presented in A\$. Refer to Note 3 Change in presentation and functional currencies.

	2023 US\$	2022 US\$	2021 A\$	2020 A\$	2020 A\$
Basic loss per share	(0.32)	(0.26)	(0.14)	(0.04)	(0.09)
Net Tangible Asset (NTA) backing per share @ June 30	(0.01)	0.14	0.58	0.17	0.12
Opthea share price @ June 30	A\$0.55	A\$1.10	A\$1.35	A\$2.36	A\$0.67

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 February 24, 2014. Under the terms of the present contract (including any subsequent board approvals relating to fixed remuneration) Dr. Baldwin:

- Receives fixed remuneration of A\$575,000 per annum from July 1, 2022 ; and
- 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:

- 12 months' notice; or
- Payment in lieu of the notice period (as detailed above) based on the fixed component of Dr. Baldwin's remuneration plus implied bonus.

## Directors' Report (cont.)

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, Dr. Baldwin 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.

Timothy Morris, CFO, is employed under an ongoing contract and employment is at will. The Company may terminate the employment without cause which provides a severance payment of 12 months base salary, 12 months of health care costs. Receives fixed remuneration of US\$475,000 per annum.

The Company may terminate Mr. Morris' 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.

Karen Adams, Vice President 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). Karen Adams may resign from her position and thus terminate this contract by giving three months' notice.

The Company may terminate Karen Adams'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.

Judith Robertson, Chief Commercial Officer, has an ongoing contract and employment is at will. The Company may terminate the employment without cause which provides a severance payment of 12 months base salary, 12 months of health care costs.

The Company may terminate Judith Robertson'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 is US\$75,000 per annum for the Chairman, US\$50,000 per annum for other US-based non-executive directors, and A\$65,700 per annum for all Australian-based non-executive directors. Base fees cover all main board activities. Membership of board committees attract the following fees: Chair Audit and Risk US\$20,000, Chair of Nominations, Clinical and Remuneration US\$10,000/A\$13,140, and general committee fees of US\$5,000/A\$6,570 per annum.

Non-executive directors are not provided with retirement benefits.

The Company implemented a Non-Executive Director share and option plan (the "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).

## Directors' Report (cont.)

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 and Phase 3 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-Emp- loyment	Long-Term	Termin- ation benefits	Share- based payment	Total US\$	Total perform- ance related %
		Salary & Fees US\$	Cash bonus <sup>1</sup> US\$	Benefit <sup>9</sup> US\$	Super- annu- ation US\$	Long Service Leave US\$	Termin- ation Pay US\$		
<b>Non-Executive directors:</b>									
Jeremy Levin	2023	75,000	-	-	-	-	350,472	425,471	82%
	2022	75,000	-	-	-	-	858,286	933,286	92%
Anshul Thakral <sup>2</sup>	2023	3,159	-	-	-	-	-	3,159	0%
	2022	-	-	-	-	-	-	-	0%
Michael Sistenich <sup>3</sup>	2023	58,201	-	-	-	-	145,079	203,280	71%
	2022	73,789	-	-	-	-	-	73,789	0%
Lawrence Gozlan <sup>3</sup>	2023	230,644	-	-	-	-	493,665	724,309	68%
	2022	70,201	-	-	-	-	586,271	656,472	89%
Daniel Spiegelman	2023	75,000	-	-	-	-	487,695	562,695	87%
	2022	75,000	-	-	-	-	696,217	771,217	90%
Julia Haller	2023	59,464	-	-	-	-	267,948	327,412	82%
	2022	55,000	-	-	-	-	587,694	642,694	91%
Susan Orr <sup>4</sup>	2023	58,928	-	-	-	-	147,267	206,195	71%
	2022	9,583	-	-	-	-	128,010	139,593	93%
Quinton Oswald <sup>5</sup>	2023	55,096	-	-	-	-	147,267	202,363	73%
	2022	9,583	-	-	-	-	128,010	137,593	93%
Judith Robertson <sup>6</sup>	2023	-	-	-	-	-	-	-	0%
	2022	27,500	-	-	-	-	358,633	386,133	93%
<b>Sub-total</b>									

## Directors' Report (cont.)

		Salary & Fees US\$	Short-Term Cash bonus <sup>1</sup> US\$	Short-Term Benefits <sup>9</sup> US\$	Post-Employment Super-annuation US\$	Long-Term Long Service Leave US\$	Termination benefits Termination Pay US\$	Share-based payment Options US\$	Total US\$	Total performance related %
Non-executive directors	2023	615,492	-	-	-	-	-	2,039,392	2,654,884	77%
	2022	395,656	-	-	-	-	-	3,343,121	3,738,777	89%
<b>Executive directors:</b>										
Megan Baldwin	2023	386,036	133,634	-	80,059	-	-	969,820	1,569,550	70%
	2022	342,510	113,475	-	34,251	-	-	730,644	1,107,405	76%
<b>Other Key Management Personnel:</b>										
Karen Adams	2023	224,126	44,290	-	36,729	-	-	202,452	507,597	49%
	2022	211,035	27,981	-	21,104	-	-	119,147	379,267	39%
Timothy Morris <sup>7</sup>	2023	327,628	36,630	40,058	-	-	-	370,630	774,946	53%
	2022	-	-	-	-	-	-	-	-	-
Judith Robertson <sup>6</sup>	2023	390,000	140,400	52,990	5,200	-	-	268,242	856,832	48%
	2022	195,000	78,000	-	-	-	-	229,060	502,060	61%
Joel Naor <sup>8</sup>	2023	450,000	-	57,259	15,180	-	-	370,935	893,374	42%
	2022	150,000	42,000	-	750	-	-	242,795	435,545	65%
<b>Totals</b>	2023	2,393,282	354,954	150,308	137,168	-	-	4,221,472	7,257,184	63%
	2022	1,294,201	261,456	-	56,105	-	-	4,664,767	6,276,529	80%

1. Bonuses are paid in the financial year following the year in which they are earned.

2. Appointed June 7, 2023.

3. Resigned June 7, 2023.

4. Director appointed April 21, 2022.

5. Director appointed April 21, 2022.

6. Director resigned January 1, 2022, appointed CCO January 1, 2022.

7. Appointed CFO October 24, 2022.

8. Appointed CMO March 1, 2022 Resigned July 15, 2023.

9. Benefits are US Health Benefits paid for US staff only.

### 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 Director share and options (NED) plans.



## Directors' Report (cont.)

### 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:

Name	During the financial year	
	Number of options granted	Number of options vested <sup>1</sup>
Daniel Spiegelman	2,000,000	412,785
Lawrence Gozlan	2,000,000	412,785
Michael Sistenich (resigned June 7, 2023)	1,500,000	309,589
Megan Baldwin	3,000,000	619,178

1. Options that are vested during the financial year were originally granted in the year ended June 30, 2023.

Options Granted during the year have the following fair values at grant date, US\$0.705 (A\$0.526), US\$0.535 (A\$0.397) and US\$0.675 (A\$0.937) with the following exercise price US\$0.948 (A\$1.27), US\$0.755 (A\$1.01) and US\$1.46 (A\$2.03), for Dr. Haller and Mrs. Robertson, Dr. Orr and Mr. Oswald and Mrs. Adams, respectively. 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.

### Performance rights over equity instruments granted as compensation

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

Name	During the financial year	
	Number of options granted	Number of options vested
Megan Baldwin	500,000	103,196
Karen Adams	150,000	30,958
Lawrence Gozlan	500,000	103,196
Daniel Spiegelman	150,000	30,958

Performance rights granted during the year have the following Fair value at Grant date US\$0.955 (A\$1.28) with a nil exercise price. All rights have an expiry of 10 years or termination date of the individual's employment. Rights vesting is conditional on performance hurdles and being employed or in office.

## Directors' Report (cont.)

### American depository security options over equity instruments granted as compensation

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

Name	During the financial year	
	Number of options granted	Number of options vested
Timothy Morris	300,000	–

American depository securities options granted during the year have the following fair value at grant date US\$3.479 (2022: US\$4.116) with an exercise price of US\$4.850 (2022: US\$6.01). All ADS options have an expiry of 10 years or termination date of the individual's employment. ADS options vesting is conditional on the individual being employed or in office.

### Exercise of options granted as compensation

During 2023, 2,033,852 shares were issued to KMP on the exercise of 6,000,000 of options previously granted as compensation.

During 2023, 4,500,000 options were exercised by the following key management personnel using the cashless exercise mechanism available under the LTIP and NED Plans. On the exercise of the options, the Company issued 533,852 ordinary shares.

The number of shares was determined by the value calculated between the market price of the shares (based on a volume weighted average price ("VWAP") for the 5 trading days prior to exercise date) of A\$0.9708 for 4,500,000 options and A\$0.855 exercise price for 1,500,000 options.

Name	No. of options exercised	No. of ordinary shares of Opthea Limited issued	Issue date	Amount unpaid	Expiry date of rights
Megan Baldwin	3,000,000	355,901	November 29 2018	\$nil	November 29, 2022
Geoffrey Kempler	1,500,000	1,500,000	November 29, 2018	\$nil	November 29, 2022
Michael Sistenich	1,500,000	177,951	November 29, 2018	\$nil	November 29, 2022
	6,000,000	2,033,852			

## Directors' Report (cont.)

### Details of options affecting current and future remuneration

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

	Number of options	Grant date	% Vested	% Forfeited <sup>1</sup>	Financial years in which grant vests	Vesting conditions
Megan Baldwin	3,000,000	November 29, 2018	100%	0%	July 1, 2019	Continued service
	3,000,000	November 16, 2022	0	0%	July 1, 2023-2026	
Jeremy Levin	750,000	January 19, 2021	25%	0%	July 1, 2020	Continued service
	750,000	January 19, 2021	0%	0%	July 1, 2021	
	750,000	January 19, 2021	0%	0%	July 1, 2022	
	750,000	January 19, 2021	0%	0%	July 1, 2023	
Michael Sistenich	1,500,000	November 29, 2018	100%	0%	July 1, 2019	Continued service
	1,500,000	November 16, 2022	0	0%	July 1, 2023	
Daniel Spiegelman	500,000	October 12, 2020	100%	0%	July 1, 2020	Continued service
	500,000	October 12, 2020	100%	0%	July 1, 2021	
	500,000	October 12, 2020	100%	0%	July 1, 2022	
	500,000	October 12, 2020	0%	0%	July 1, 2023	
	2,000,000	November 16, 2022	0%	0%	July 1, 2023	
Lawrence Gozlan	500,000	October 12, 2020	100%	0%	July 1, 2020	Continued service
	500,000	October 12, 2020	100%	0%	July 1, 2021	
	500,000	October 12, 2020	100%	0%	July 1, 2022	
	500,000	October 12, 2020	0%	0%	July 1, 2023	
	2,000,000	November 16, 2022	0%	0%	July 1, 2023	
Julia Haller	500,000	October 19, 2021	100%	0%	July 1, 2021	Continued service
	500,000	October 19, 2021	100%	0%	July 1, 2022	
	500,000	October 19, 2021	0%	0%	July 1, 2023	
	500,000	October 19, 2021	0%	0%	July 1, 2024	
Susan Orr	250,000	April 24, 2022	100%	0%	July 1, 2022	Continued service
	250,000	April 24, 2022	100%	0%	July 1, 2023	
	250,000	April 24, 2022	0%	0%	July 1, 2024	
	250,000	April 24, 2022	0%	0%	July 1, 2025	
Quinton Oswald	250,000	April 24, 2022	100%	0%	July 1, 2022	Continued service
	250,000	April 24, 2022	100%	0%	July 1, 2023	
	250,000	April 24, 2022	0%	0%	July 1, 2024	
	250,000	April 24, 2022	0%	0%	July 1, 2025	

1. 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.

## Directors' Report (cont.)

	Number of options	Grant date	% Vested	% Forfeited <sup>1</sup>	Financial years in which grant vests	Vesting conditions
Judith Robertson	500,000	October 19, 2021	100%	0%	July 1, 2021	Continued service
	500,000	October 19, 2021	100%	0%	July 1, 2022	
	500,000	October 19, 2021	0%	0%	July 1, 2023	
	500,000	October 19, 2021	0%	0%	July 1, 2024	
Karen Adams	200,000	June 6, 2022	100%	0%	July 1, 2022	Continued service
	200,000	June 6, 2022	100%	0%	July 1, 2023	
	200,000	June 6, 2022	0%	0%	July 1, 2024	
	200,000	June 6, 2022	0%	0%	July 1, 2024	

1. 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.

### Details of performance rights affecting current and future remuneration

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

	Number of rights	Grant date	% Vested	% Forfeited <sup>1</sup>	Financial years in which grant vests	Vesting conditions
Megan Baldwin	100,000	October 19, 2021	100%	0%	July 1, 2022	Continued service
	100,000	October 19, 2021	100%	0%	July 1, 2023	Continued service
	100,000	October 19, 2021	0%	0%	July 1, 2024	Continued service
	150,000	October 19, 2021	0%	0%	July 1, 2024	KPIs
	150,000	October 19, 2021	0%	0%	July 1, 2024	KPIs
	400,000	October 19, 2021	0%	0%	July 1, 2024	KPIs
	400,000	October 19, 2021	0%	0%	July 1, 2024	KPIs
	200,000	October 19, 2021	0%	0%	July 1, 2024	KPIs
	500,000	November 16, 2022	100%	0%	July 1, 2023	Continued service
Karen Adams	150,000	November 16, 2022	100%	0%	July 1, 2023	Continued service
Lawrence Gozlan	500,000	November 16, 2022	100%	0%	July 1, 2023	Continued service
Daniel Spiegelman	150,000	November 16, 2022	100%	0%	July 1, 2023	Continued service

1. 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.

## Directors' Report (cont.)

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

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

	Number of ADS options	Grant date	% Vested	% Forfeited <sup>1</sup>	Financial years in which grant vests	Vesting conditions
Timothy Morris	75,000	October 24, 2022	0%	0%	July 1, 2023	Continued Service
	75,000	October 24, 2022	0%	0%	July 1, 2024	Continued service
	75,000	October 24, 2022	0%	0%	July 1, 2025	Continued service
	75,000	October 24, 2022	0%	0%	July 1, 2026	Continued service
Joel Naor	75,000	March 1, 2023	100%	0%	July 1, 2022	Continued service
	6,250 monthly for 36 months	April 1, 2023 – Mar 1, 2026	8.33%	0%	July 1, 2023 – 2026	Continued service

1. 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.

### Options over equity instruments

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

Number of options:		Held at July 1	Granted as compensation	Options exercised	Lapsed	Forfeited	Held at June 30	Vested during the year	Vested and exercisable
Megan Baldwin	2023	3,000,000	3,000,000	3,000,000	-	-	3,000,000	619,178	619,178
	2022	3,000,000	-	-	-	-	3,000,000	-	3,000,000
Jeremy Levin	2023	3,000,000	-	-	-	-	3,000,000	750,000	2,250,000
	2022	3,000,000	-	-	-	-	3,000,000	750,000	1,500,000
Geoffrey Kempler <sup>1</sup>	2023	1,500,000	-	1,500,000	-	-	-	-	-
	2022	1,500,000	-	-	-	-	1,500,000	-	1,500,000
Daniel Spiegelman	2023	2,000,000	2,000,000	-	-	-	4,000,000	912,785	1,912,785
	2022	2,000,000	-	-	-	-	2,000,000	500,000	1,000,000
Lawrence Gozlan	2023	2,000,000	2,000,000	-	-	-	4,000,000	912,785	1,912,785
	2022	2,000,000	-	-	-	-	2,000,000	500,000	1,000,000
Michael Sistenich	2023	1,500,000	1,500,000	1,500,000	-	-	1,500,000	309,589	309,589
	2022	1,500,000	-	-	-	-	1,500,000	-	1,500,000
Julia Haller	2023	2,000,000	-	-	-	-	2,000,000	500,000	1,000,000
	2022	2,000,000	-	-	-	-	2,000,000	500,000	500,000

1. Geoffrey Kempler resigned October 12, 2020.

## Directors' Report (cont.)

Number of options:		Held at July 1	Granted as compensation	Options exercised	Lapsed	Forfeited	Held at June 30	Vested during the year	Vested and exercisable
Susan Orr	2023	1,000,000	-	-	-	-	1,000,000	250,000	500,000
	2022	-	1,000,000	-	-	-	1,000,000	250,000	250,000
Quinton Oswald	2023	1,000,000	-	-	-	-	1,000,000	250,000	500,000
	2022	-	1,000,000	-	-	-	1,000,000	250,000	250,000
<b>Other executives:</b>									
Karen Adams	2023	800,000	-	-	-	-	800,000	400,000	400,000
	2022	-	800,000	-	-	-	800,000	200,000	200,000
Judith Robertson	2023	2,000,000	-	-	-	-	2,000,000	500,000	1,000,000
	2022	-	2,000,000	-	-	-	2,000,000	500,000	500,000
<b>Total</b>	2023	19,800,000	8,500,000	6,000,000	-	-	22,300,000	5,204,337	9,654,337
	2022	13,000,000	6,800,000	-	-	-	19,800,000	3,450,000	11,200,000

Number of performance rights		Held at July 1	Granted as compensation	Rights exercised	Lapsed	Forfeited	Held at June 30	Vested during the year	Vested and exercisable
Megan Baldwin	2023	1,600,000	500,000	-	-	-	2,100,000	203,196	272,785
	2022	-	1,600,000	-	-	-	1,600,000	69,589	69,589
Lawrence Gozlan	2023	-	500,000	-	-	-	500,000	103,196	103,196
	2022	-	-	-	-	-	-	-	-
Daniel Spiegelman	2023	-	150,000	-	-	-	150,000	30,959	30,959
	2022	-	-	-	-	-	-	-	-
Karen Adams	2023	-	150,000	-	-	-	150,000	30,959	30,959
	2022	-	-	-	-	-	-	-	-
<b>Total</b>	2023	1,600,000	1,300,000	-	-	-	2,900,000	368,311	437,900
	2022	-	1,600,000	-	-	-	1,600,000	69,589	69,589

Number of ADS options		Held at July 1	Granted as compensation	ADS options exercised	Lapsed	Forfeited	Held at June 30	Vested during the year	Vested and exercisable
Timothy Morris	2023	-	300,000	-	-	-	300,000	-	-
	2022	-	-	-	-	-	-	-	-
Joel Naor	2023	300,000	-	-	-	-	300,000	93,750	-
	2022	-	-	-	-	-	-	-	-
<b>Total</b>	2023	300,000	300,000	-	-	-	600,000	93,750	-
	2022	-	300,000	-	-	-	300,000	-	-

## Directors' Report (cont.)

### 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 July 1	Granted as remuneration	On Exercise of Quoted Options	Purchased in the year	Sold during the year	Balance at end of period June 30
<b>Non-executive directors</b>							
Jeremy Levin	2023	–	–	–	31,496	–	31,496
	2022	–	–	–	–	–	–
Geoffrey Kempler <sup>1</sup>	2023	2,326,797	–	1,500,000	–	–	3,826,797
	2022	2,326,797	–	–	–	–	2,326,797
Michael Sistenich (resigned June 7, 2023)	2023	1,233,097	–	177,951	–	–	1,411,048
	2022	1,233,097	–	–	–	–	1,233,097
Daniel Spiegelman	2023	–	–	–	–	–	–
	2022	–	–	–	–	–	–
Lawrence Gozlan	2023	1,877,357	–	–	–	–	1,877,357
	2022	1,877,357	–	–	–	–	1,877,357
Julia Haller	2023	–	–	–	–	–	–
	2022	–	–	–	–	–	–
Susan Orr	2023	–	–	–	–	–	–
	2022	–	–	–	–	–	–
Quinton Oswald	2023	–	–	–	–	–	–
	2022	–	–	–	–	–	–
Anshul Thrakul (appointed June 7, 2023)	2023	–	–	–	–	–	–
	2022	–	–	–	–	–	–
<b>Executives</b>							
Megan Baldwin	2023	3,839,398	–	355,901	–	–	4,195,299
	2022	3,839,398	–	–	–	–	3,839,398
Karen Adams	2023	–	–	–	–	–	–
	2022	–	–	–	–	–	–
Judith Robertson	2023	–	–	–	–	–	–
	2022	–	–	–	–	–	–
Joel Naor	2023	–	–	–	–	–	–
	2022	–	–	–	–	–	–
Timothy Morris <sup>2</sup>	2023	–	–	–	–	–	–
	2022	–	–	–	–	–	–
<b>Total</b>	2023	9,276,649	–	533,852	31,496	–	9,841,997
	2022	9,276,649	–	–	–	–	9,276,649

1. Geoffrey Kempler resigned as at October 12, 2020.

2. Appointed CFO October 24, 2022.

## Directors' Report (cont.)

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 September 28, 2023.

For and on behalf of the board:

A handwritten signature in black ink, appearing to be 'Megan Baldwin', written in a cursive style.

Megan Baldwin  
CEO & Managing Director  
Opthea Limited

Melbourne  
September 28, 2023



## 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 Opthea in 2008, she 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, Dr. Baldwin 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. Megan holds a PhD in Medicine from the University of Melbourne, having conducted her doctoral studies at the Ludwig Institute for Cancer Research. Dr. Baldwin is on the board of Ausbiotech and is a member of the Australian Institute of Company Directors.



### Timothy Morris

Chief Financial Officer

Timothy Morris was appointed Chief Financial Officer of Opthea in October 2022. He has over 25 years of experience in the role of Chief Financial Officer with public biotechnology companies. His financial and business development experience spans clinical to commercial stage companies engaged in developing small molecules, biologics and cell therapy. Previously, Mr. Morris was Chief Financial Officer of Iovance Biotherapeutic (NASDAQ:IOVA) which raised over US\$1 billion in four offerings to fund expansion of the clinical development program, build manufacturing capability and to prepare for commercialization. He serves as a Non-Executive Director for DBV Technologies S.A., Aquestive Therapeutics, Univercells S.A. and Humanetics Corporation. Mr. Morris holds a Bachelor of Science in Business from California State University, Chico.



### Karen Adams

B.BUS, CPA, GAICD, FCG, FGIA  
Vice President Finance and  
Company Secretary

Karen Adams was appointed Vice President Finance in May 2021 and Company Secretary in June 2021. Karen 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, Karen was the Chief Financial Officer of the Victor Smorgon Group in Melbourne.

Karen has over 20 years' experience of financial management in board-level positions for private and listed companies in Australia, UK, the US and Ireland. Karen holds a Graduate Degree in Business from Swinburne University and is a member of the Australian Society of Chartered Accountants, Graduate of the Australian Institute of Company Directors and a Fellow of the Institute of Company Secretaries. Karen is also the Company Secretary of the Company's subsidiary, Vegenics Pty Ltd.

## Management Team (cont.)



### Judith Robertson

MBA  
Chief Commercial Officer

Judith Robertson was appointed Chief Commercial Officer of Opthea in January 2022.

Ms. Robertson was most recently Chief Commercial Officer of Eleusis Ltd and serves on the board of Durect Corporation, a Nasdaq-listed company developing therapies for acute organ injury and chronic liver diseases. She was previously Chief Commercial Officer of Aerie Pharmaceuticals where she oversaw the launch of Rhopressa®, the first product in 20 years to target a new mechanism of action for the treatment of glaucoma, and the launch of the combination product Rocklatan®, the first fixed-dose combination of a prostaglandin and ROCK inhibitor for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. Prior to Aerie, Ms. Robertson was Vice President Immunology and Ophthalmology Global Commercial Strategy Leader at Johnson and Johnson, Janssen Pharmaceuticals, and Vice President, Ophthalmology Global Business Franchise Head at Novartis (formerly Alcon). Ms. Robertson's prior experience also includes sales and marketing roles at Novartis, Bristol Myers Squibb and Searle USA.

Ms. Robertson earned a BA with honors from Ryerson University, Canada. She also holds an MBA from Northwestern University, Kellogg School of Management.



### Bruno Gagnon

BPharm, MSc  
Senior Vice President,  
Global Clinical Operations

Mr. Gagnon was appointed Chief Commercial Officer of Opthea in July 2022.

Mr. Gagnon leads Global Clinical Operations and was former Sr. Vice President of Development Operations at Eidos Therapeutics, a BridgeBio company in San Francisco, CA. He also served as Vice President of Clinical Operations at BioMarin Pharmaceutical. Previously, Mr. Gagnon held positions of increasing responsibilities at Roche Diagnostics, Chiron and Hoechst Marion Roussel (now Sanofi). Over his 30-year career, functions under his leadership have included Global Clinical Trial Management, Patient Advocacy, Medical Writing, Outsourcing and Contracts, Supply Chain Management, Clinical Data Management, Clinical Systems, Document Management and Clinical Training.

Mr. Gagnon holds a bachelor's degree from the School of Pharmacy, Laval University and a Master's in Pharmaceutical Sciences from University of Montreal, both in Quebec, Canada.



### Mike Gerometta

PhD  
Head of CMC Development

Mike Gerometta has been Head of Chemistry, Manufacturing & Controls (CMC) Development for Opthea since 2008 with responsibilities encompassing outsourcing of Opthea's biopharmaceutical research and cGMP manufacturing activities. Mike has over 30 years' experience in the Australian biotechnology industry, working with numerous contract manufacturing organizations 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 global regulatory interactions.

Previously as Chief Operating Officer of Q-Gen, the manufacturing facility of the Queensland Institute of Medical Research, he restructured the service business to align with QIMR's 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 Development Director. Mike was awarded his PhD in biotechnology from the Queensland University of Technology and has a degree in chemistry from the University of Technology in Sydney.

## Management Team (cont.)



### Mark O' Neill

MSc, B. Chem Eng  
Vice President CMC

Mark O'Neill was appointed Vice President CMC in January 2022.

Mr. O'Neill was most recently head of Process Development for Avexis Gene therapies where he orchestrated all product development and technical operations activities pertaining to the startup and licensure of Zolgensma drug substance manufacturing at the Colorado site. Prior to Avexis, he was Vice President and General Manager of the Thermo Fisher Groningen Single Use Biologics Manufacturing Facility in Groningen, The Netherlands, where he oversaw all operations including startup of commercial manufacturing and initial commercial licensure at the facility. Mr. O'Neill has over 30 years of experience in the manufacturing of biopharmaceuticals including 20 years with Amgen where he gained extensive experience in all aspects of lifecycle management including Quality, Engineering, Production, Development, Supply Chain and Business Development.

Mark holds a Master of Science Degree from Colorado School of Mines in Environmental and Chemical Engineering and a Bachelor's of Science Degree in Chemical Engineering from the University of Colorado.



### Ian Leitch

PhD  
Director – Clinical Research

Ian 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.

# Financial Report

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# Consolidated Statement of Profit or Loss and Other Comprehensive Income

For the year ended June 30, 2023

	Note	2023 US\$	2022 US\$
Revenue	7	108,406	90,683
Other income	8	276,869	108,322
Research and development expenses	9	(122,128,314)	(78,654,217)
Patent and intellectual property expense		(166,826)	(160,501)
Interest expense on DFA*	12	(13,462,160)	(28,713)
Administrative expenses	10	(28,115,929)	(17,922,419)
Finance income	11	3,227,496	235,468
Fair value adjustment gain on DFA	13	12,302,160	-
Net foreign exchange loss	14	(489,137)	(2,813,993)
Loss before income tax		(148,447,435)	(99,116,657)
Income tax benefit	15	5,926,350	6,299,286
<b>Loss for the year</b>		<b>(142,521,085)</b>	<b>(92,817,371)</b>
Other comprehensive income			
Items that will not be reclassified subsequently to profit or loss:			
Fair value gains on investments in financial assets		-	-
Other comprehensive income for the year, net of tax		-	-
<b>Total comprehensive loss for the year</b>		<b>(142,521,085)</b>	<b>(92,817,371)</b>
Loss for the year is attributable to:			
Owners of the Company	28	(142,521,085)	(92,817,371)
		<b>(142,521,085)</b>	<b>(92,817,371)</b>
Total comprehensive loss for the year is attributable to:			
Owners of the Company		(142,521,085)	(92,817,371)
		<b>(142,521,085)</b>	<b>(92,817,371)</b>
Loss per share attributable to the owners of the Company:			
- Basic and diluted loss per share (cents)	16	(32.20)	(26.40)

\* Development Funding Agreement ("DFA").

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 June 30, 2023

	Note	2023 US\$	2022 US\$
<b>Assets</b>			
<b>Current assets</b>			
Cash and cash equivalents	17	89,188,713	44,631,293
Current tax receivable	15	5,926,350	6,299,286
Receivables	18	636,564	257,668
Prepayments	19	2,634,671	8,720,195
<b>Total current assets</b>		<b>98,386,298</b>	<b>59,908,442</b>
<b>Non-current assets</b>			
Equipment		33,035	28,082
Right-of-use asset	20	168,451	-
Prepayments	21	53,535	110,295
<b>Total non-current assets</b>		<b>255,021</b>	<b>138,377</b>
<b>Total assets</b>		<b>98,641,319</b>	<b>60,046,819</b>
<b>Liabilities</b>			
<b>Current liabilities</b>			
Payables	22	17,891,854	11,445,498
Lease liabilities		97,485	-
Provisions	23	753,300	596,203
<b>Total current liabilities</b>		<b>18,742,639</b>	<b>12,041,701</b>
<b>Non-current liabilities</b>			
Lease liabilities	24	84,226	-
Financial liabilities	25	85,660,000	-
Provisions	26	7,631	27,974
<b>Total non-current liabilities</b>		<b>85,751,857</b>	<b>27,974</b>
<b>Total liabilities</b>		<b>104,494,497</b>	<b>12,069,675</b>
<b>Net assets</b>		<b>(5,853,178)</b>	<b>47,977,144</b>
<b>Equity</b>			
Contributed equity	27	320,883,552	235,277,217
Accumulated losses	28	(359,462,438)	(216,941,353)
Reserves	28	32,725,708	29,641,280
<b>Total equity</b>		<b>(5,853,178)</b>	<b>47,977,144</b>

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 June 30, 2023

	Note	Contributed equity US\$	Pre-funded warrants US\$	Share-based payments reserve US\$	Fair value of investments reserve US\$	FX translation reserve US\$	Accumulated losses US\$	Total equity US\$
As at July 1, 2021		234,147,526	-	4,087,650	1,085,411	20,089,163	(124,123,982)	135,285,768
Loss for the year*		-	-	-	-	-	(92,817,371)	(92,817,371)
Total comprehensive income and expense for the period		-	-	-	-	-	(92,817,371)	(92,817,371)
Recognition of share-based payment	28	-	-	5,251,572	-	-	-	5,251,572
Issue of ordinary shares on the exercise of options	27	1,129,691	-	(872,516)	-	-	-	257,175
<b>Balance at June 30, 2022</b>		<b>235,277,217</b>	<b>-</b>	<b>8,466,706</b>	<b>1,085,411</b>	<b>20,089,163</b>	<b>(216,941,353)</b>	<b>47,977,144</b>
<b>As at July 1, 2022</b>		<b>235,277,217</b>	<b>-</b>	<b>8,466,706</b>	<b>1,085,411</b>	<b>20,089,163</b>	<b>(216,941,353)</b>	<b>47,977,144</b>
Loss for the year*		-	-	-	-	-	(142,521,085)	(142,521,085)
Total comprehensive income and expense for the period		-	-	-	-	-	(142,521,085)	(142,521,085)
Issuance of ordinary shares		81,815,357	-	-	-	-	-	81,815,357
Recognition of share-based payment	28	-	-	5,834,686	-	-	-	5,834,686
Issue of ordinary shares on the exercise of options	27	3,790,978	-	(2,750,258)	-	-	-	1,040,720
<b>Balance at June 30, 2023</b>		<b>320,883,552</b>	<b>-</b>	<b>11,551,134</b>	<b>1,085,411</b>	<b>20,089,163</b>	<b>(359,462,438)</b>	<b>(5,853,178)</b>

\* 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 June 30, 2023

	Note	2023 US\$	2022 US\$
<b>Cash flows from operating activities</b>			
Interest received		3,121,594	216,422
Royalty and license income received		3,826	90,683
Grant and other income		276,869	455,807
Payment of lease interest		(17,148)	(5,920)
Payments to suppliers, employees and for research & development and intellectual property costs (inclusive of GST)		(130,292,806)	(77,064,842)
Research and development tax incentive scheme credit received in cash		6,299,286	4,972,898
Net cash flows used in operating activities	31	(120,608,379)	(71,334,952)
<b>Cash flows from investing activities</b>			
Purchase of equipment		(21,954)	(16,910)
Net cash flows used in investing activities		(21,954)	(16,910)
<b>Cash flows from financing activities</b>			
Payment of lease liabilities		(70,966)	(85,578)
Net proceeds on issue of shares		81,815,358	-
Net proceeds under the Development Funding Agreement	25	84,500,000	-
Cash received for ordinary shares issued on exercise of options	27	1,040,718	257,175
Net cash flows provided by financing activities		167,285,110	171,597
Net increase/(decrease) in cash and cash equivalents		46,654,777	(71,180,265)
Effects of exchange rate changes on the balance of cash held in foreign currencies		(2,097,357)	(2,381,619)
Cash and cash equivalents at beginning of year		44,631,293	118,193,177
<b>Cash and cash equivalents at the end of the year</b>	<b>17</b>	<b>89,188,713</b>	<b>44,631,293</b>

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 Group'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*, Australian 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.

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 authorized for issue by the directors on August 31, 2023.

### Going Concern

For the year ended June 30, 2023, the Group incurred a loss after income tax of \$142,521,085 (2022: \$92,817,371) and had net cash outflows from operating activities of \$120,608,379 (2022: \$71,334,952). As at June 30, 2023, the Group had cash and cash equivalents of \$89,188,713 (2022: \$44,631,293), net current assets of \$79,643,659 (2022: \$47,866,741), and was in a negative net asset position of \$ 5,853,178 (2022: positive \$47,977,144).

The consolidated financial statements have been prepared on a going concern basis, which contemplates continuity of normal activities and realization of assets and settlement of liabilities in the normal course of business. As the Group is still in the research and development phase, the ability of the Group to continue its development activities as a going concern is dependent upon it deriving sufficient cash from investors and from funding provided under the Development Funding Agreement ('DFA or Agreement') with Carlyle and Abingworth. Of the initial total funding of US\$120 million, US\$50 million was received by the Group in September 2022 and another US\$35 million was received in December 2022. The Group expects to receive the remaining US\$35 million no later than December 31, 2023.

Subsequent to June 30, 2023, the Group was notified that a new co-investor of Carlyle and Abingworth intends to participate in a funding under the DFA of US\$50 million to increase total DFA funding from US\$120 million to US\$170 million, which is subject to the co-investor's final due diligence and receipt of regulatory and tax approvals, appropriate documentation and compliance with closing conditions. Upon completion of the final due diligence, receipt of regulatory and tax approvals, execution of the appropriate documentation and satisfaction of the closing conditions, the Group expects to receive the additional US\$50 million. While the Group anticipates that the due diligence will be completed to the satisfaction of the co-investor, the necessary approvals will be obtained, the appropriate documentation will be executed and that all closing conditions will be satisfied, there is no assurance that the Group will ultimately receive the additional US\$50 million. If the additional US\$50 million is not received by June 30, 2024, the Group will need to raise additional funds or reduce expenditures to continue as a going concern.

Concurrently with the receipt of the notice from the co-investor to increase its investment, the Group entered into binding commitments for the private placement of ordinary shares and entitlement rights and accompanying options for aggregate gross proceeds of approximately A\$90 million (US\$58 million) (the 'Equity Financing'). The Equity Financing consists of two closings, of which the first closing of A\$73 million (US\$47 million) consisting of a placement offering and an acceleration portion of an Accelerated Non-Renounceable Entitlement Offer ("ANREO") occurred on September 1, 2023. The second closing of A\$17 million (US\$11 million), representing the remaining institutional and retail portion of the ANREO, on September 20, 2023. The shares were issued and cash received on September 20, 2023. See Note 37, Events after the balance sheet date, for further information.

## Notes to the Consolidated Financial Statements (cont.)

While we expect that with our cash on hand at June 30, 2023 of \$89 million, together with the net proceeds from the Equity Offering and the \$85 million expected under the Funding Agreement, we will be able to fund our operations through the third calendar quarter of 2024, such proceeds will not be sufficient to fully fund all anticipated costs of the Phase 3 clinical trials to top-line data. We will need to raise significant funds to complete the efficacy and safety phase of both studies and to report top-line data.

The Directors and management have considered the cash flow forecasts including the funding requirements of the business as well as the funding expected to be raised through the Agreement and Offer. They have also considered the Group's key risks and uncertainties affecting the likely development of the business, as well as the conditions set forth in the Agreement. Based on this assessment, the Directors and management believe that the conditions in the DFA can be met and that the Group has adequate resources to continue normal activities and realize its assets and settle its liabilities in the normal course of business. Accordingly, the directors have prepared the financial statements on the going concern basis.

Should the Group not be able meet the conditions in the DFA to increase the total funding from US\$120 million to US\$170 million, the Group will need to raise additional funds or reduce expenditures to continue as a going concern. Based on that, a material uncertainty exists which may cast significant doubt as to whether the Group will continue as a going concern. The financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or to the amounts and classification of liabilities that might be necessary should the Group not continue as a going concern.

### 3. Summary of accounting policies

The consolidated financial statements have been prepared using the significant accounting policies and measurement bases summarized 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 United States dollars unless otherwise stated.

#### Functional currencies

An entity's functional currency is the currency of the primary economic environment in which the entity operates. The Group's functional currency is US dollars.

#### Change in presentation of Other income

In the current financial year the Group changed its presentation of Other income by reclassifying interest income out of Other income and into Finance Income – interest income to better reflect the nature of the related amounts as finance income. This reclassification had no effect on the reported results of operations. The comparative year has also been reclassified.

#### Basis of consolidation

The consolidated financial statements incorporate the financial statements of 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.

Consolidation of a subsidiary begins when the Company obtains control over the subsidiary and ceases when the Company loses control of the subsidiary.

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

As at January 1, 2021 it was determined that the Group's functional and presentation currency had changed from Australian dollars to United States dollars. Therefore, the functional and presentation currency of the Group is United States dollars (US\$).

### 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.

## Financial assets and liabilities

### Recognition and derecognition of financial assets

Purchases and sales of financial assets that require delivery of assets within the time frame generally established by regulation or convention in the marketplace are recognized on the trade date, i.e., the date that the Group commits to purchase the asset. Financial assets are derecognized 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 derecognizes the asset if it has transferred control of the assets.

When financial assets are recognized initially, they are measured at fair value, plus directly attributable transaction costs.

### 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.

### Other receivables

Other receivables generally comprise bank interest receivable, other receivables from external parties and Goods and Services Tax (GST) credits receivable and are recognized and carried at original invoice amount less an allowance for any uncollectible amounts. The amounts are usually received within 30 to 60 days of recognition.

The Group measures the loss allowance for receivables at an amount equal to lifetime expected credit losses (ECL). The ECL on receivables are estimated under the simplified approach as permitted under AASB 9 *Financial Instruments*. This uses a provision matrix by reference to past experience of the debtor and an analysis of the debtor's current financial position, adjusted for factors that are specific to the debtors and general economic conditions of the industry in which the debtors operate.

The Group writes off a receivable when there is information indicating that the debtor is in severe financial difficulty and there is no realistic prospect of recovery.

### Investments

Investments in financial assets comprise of the Group's non-current investments in listed companies.

On initial recognition, the Group may make an irrevocable election (on an instrument-by-instrument basis) to designate investments in equity instruments as fair value through other comprehensive income (FVTOCI). Designation at FVTOCI is not permitted if the equity instrument is held for trading.

## Notes to the Consolidated Financial Statements (cont.)

Investments in equity instruments at FVTOCI are initially measured at fair value plus transaction costs. Subsequently, they are measured at fair value with gains or losses arising from changes in the fair value recognized in other comprehensive income and accumulated in the fair value of investments reserve. The fair values of investments in financial assets that are actively traded in organized financial markets is determined by reference to quoted market bid prices at the close of business on the reporting date. The cumulative gain or loss is not reclassified to profit or loss on disposal of the equity instruments.

Dividends on these investments in equity instruments are recognized in profit or loss in accordance with Australian Accounting Standards.

### Finance income

Almost all of the Group's finance income is earned on short-term bank deposits, and as such, finance income is recognized when the Group's right to receive the payment is established.

### Payables

Payables are carried at amortized 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.

### Financial liabilities

Financial liabilities are recognized in the Group's statement of financial position when the Group becomes a party to the contractual provisions of the instrument. Financial liabilities are initially measured at fair value. Transaction costs that are directly attributable to the acquisitions or issue of financial liabilities (other than financial liabilities at fair value through profit or loss) are deducted from the fair value of the financial liabilities, as appropriate, on initial recognition. Subsequent measurement of the liability will be at its amortized cost, subject to any re-measurement of the obligation for changes in assumptions.

### *Amortized cost and effective interest method*

The effective interest method is a method of calculating the amortized cost of an instrument and of allocating interest expense over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash payments through the expected life of the financial liability, or (where appropriate) a shorter period, to the amortized cost of the financial liability.

Interest expense is recognized in profit and loss and is included in the "Interest expense on DFA" line item.

### *Revaluation*

At every reporting period, the Company will review the expected approval and commercial launch dates. If the dates are delayed from those used at previous reporting period, it is expected that a revaluation will result in another non-cash gain. If the timelines for approval and launch are accelerated, the Company would anticipate a revaluation resulting in a non-cash charge to be recognized on the Profit and Loss statement. The gains or losses are unrealized.

## Equipment

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; and
- Leasehold improvements – 8 years or the term of the lease if shorter.

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

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

# Notes to the Consolidated Financial Statements (cont.)

## 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 recognized 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.

As of June 30, 2023 and 2022, the Group is in the research phase and has not capitalized any development costs to date.

## 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 recognized 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 recognized 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 recognized 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 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 recognized, together with a corresponding increase in equity, over the period in which the performance conditions are considered achievable (the vesting period), ending on the date on which the relevant employees become fully entitled to the award (the vesting date).

The charge to profit or loss for the period is the cumulative amount 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.

## 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.

# Notes to the Consolidated Financial Statements (cont.)

## Revenue recognition

License revenue in connection with licensing of the Group's intellectual property (including patents) to customers is recognized as a right to use the Group's intellectual property as it exists at the point in time in which the license is granted. This is because the contracts for the license of intellectual property are distinct and do not require, nor does the customer reasonably expect, that the Group will undertake further activities that significantly affect the intellectual property to which the customer has the rights. Although the Group is entitled to sales-based royalties from the eventual sales of goods and services to third parties using the intellectual property licensed, these royalty arrangements do not in themselves indicate that the customer would reasonably expect the Group to undertake such activities, and no such activities are undertaken or contracted in practice. Accordingly, the promise to provide rights to the Group's intellectual property is accounted for as a performance obligation satisfied at a point in time.

The following consideration is received in exchange for licenses of intellectual property:

- Up-front license fees – these are fixed amounts and are recognized at the point in time when the Group transfers the intellectual property to the customer.
- Sales-based royalties – these are variable consideration amounts promised in exchange for the license of intellectual property and are recognized when the sales to third parties occur given the performance obligation to transfer the intellectual property to the customer is already satisfied.

During the years ended June 30, 2023 and 2022, the Group's only revenue related to sales-based royalties.

## Income tax

### Current 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.

### Research and development tax incentive

The Research and Development (R&D) Tax Incentive Scheme is an Australian Federal Government program under which eligible companies with annual aggregated revenue of less than A\$20 million can receive cash amounts equal to 43.5% of eligible research and development expenditures from the Australian Taxation Office (ATO). The R&D Tax Incentive Scheme incentive relates to eligible expenditure incurred in Australia and, under certain circumstances, overseas on the development of the Group's lead candidate, OPT-302. The R&D tax incentive is applied annually to eligible expenditure incurred during the Group's financial year following annual application to AusIndustry, an Australian governmental agency, and subsequent filing of its Income Tax Return with the ATO after the financial year end.

The Group estimates the amount of R&D tax incentive after the completion of the financial year based on eligible Australia and overseas expenditures incurred during that year.

The Group has presented incentives in respect of the R&D Tax Incentive Scheme within income tax benefit in the Statement of Profit or Loss and Other Comprehensive Income by analogizing with AASB 112 *Income Taxes*.

### Deferred tax

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 recognized 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.

## Notes to the Consolidated Financial Statements (cont.)

Deferred income tax assets are recognized 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 utilized, 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.

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 utilized.

Unrecognized deferred income tax assets are reassessed at each reporting date and are recognized 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 realized 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 recognized directly in equity are recognized directly in equity and not in profit or loss.

### Tax consolidation legislation

Tax consolidation is a system adopted by the ATO that treats a group of entities as a single entity for tax purposes. Opthea Limited and its 100% owned Australian domiciled subsidiary formed a tax consolidated group effective July 1, 2003. The head entity, Opthea Limited, and its controlled entity, Vegenics Pty Ltd, are current members of the tax consolidated group and 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.

The head entity, which is the parent entity, in assuming the net unused tax losses and unused relevant tax credits, has recognized 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 recognized the difference as a distribution from subsidiaries in profit or loss.

### Other taxes

Revenues, expenses, assets and liabilities are recognized 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 recognized 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.

## 4. Critical accounting judgments and key sources of estimation uncertainty

In applying the Group's accounting policies, management continually evaluates judgments, estimates and assumptions based on experience and other factors, including expectations of future events that may have an impact on the Group. All judgments, 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 judgments, estimates and assumptions.

# Notes to the Consolidated Financial Statements (cont.)

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

## 4.1 Critical judgments 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 years ended June 30, 2023 and 2022, Opthea progressed Phase 3 wet age-related macular degeneration (wet AMD) trials. A key measure of Opthea's performance is the level of expenditure incurred on the research of OPT-302.

Judgment is required in relation to:

- The classification of expenses in the income statement between research and development costs and operating expenses; and
- Whether costs relate to R&D, and consequently if they meet the capitalization criteria under AASB 138 *Intangible Assets*.

The directors have determined that the Group is still in a research phase and accordingly, no development costs have been capitalized as of June 30, 2023 and 2022.

### Taxation

#### Research and development tax incentive

The Research and Development (R&D) Tax Incentive Scheme is an Australian Federal Government program under which eligible companies can receive cash refunds of 43.5% of eligible R&D expenditure. Judgments are required as to the R&D tax incentive refundable offset eligibility in respect of:

- The Group's ability to make claims and its continued compliance under the scheme;
- R&D and other supporting costs previously approved by Australian tax authorities; and
- Estimated amounts, timing and geographical location of costs related to the projects for which applications have been approved to date; and Assessment of whether expenditure on projects for which approval has been given by Australian tax authorities relate to Australian or overseas expenditure.

For the years ended June 30, 2023 and 2022, the Group has recognized an R&D tax incentive receivable of \$6 million and \$6.3 million respectively within the Consolidated Statement of Financial Position, with a corresponding amount recognized within income tax benefit within the Consolidated Statement of Profit or Loss and Other Comprehensive Income.

The R&D tax incentive receivable as at June 30, 2023 and 2022 is based on the legislation as currently enacted as at June 30, 2023 and 2022, respectively. Any proposed changes to the legislation, such as rate changes and eligibility requirements, may have a retrospective impact if the legislation is passed. During the year, no such changes have occurred.

Investment tax credits such as the R&D tax incentive are outside of the scope of AASB 112 *Income Taxes* and AASB 120 *Accounting for Government Grants and Disclosure of Government Assistance*. Based on the guidance in AASB 108 *Accounting Policies, Changes in Accounting Estimates and Errors*, companies need to make an accounting policy choice on how to present these incentives, which in practice is done by either analogizing with AASB 112 or with AASB 120.

In the Group's opinion, the R&D tax incentive should be presented by analogizing to AASB 112 because the nature of the incentive is considered to be more closely aligned to income taxes, based on the following considerations:

- The R&D tax incentive is considered an income tax offset which will be offset against the Group's tax obligation if and when the Group returns to a net tax payable position. In addition, whilst the Group is currently eligible to receive cash payments under the scheme since its consolidated revenue is currently below \$20 million, if and when the Group generates revenue in excess of \$20 million the R&D tax incentive will become non-refundable and can only be offset against any future income tax payable by the Group.
- The ATO, which is the tax authority in Australia, manages the annual claims process as the R&D tax incentive is included in the Group's annual income tax return.

The ATO is also responsible for making the R&D tax incentive cash payment if a company is eligible for a cash refund under the program, oversees compliance with the requirements of the R&D tax incentive scheme and performs pre-issuance reviews.



# Notes to the Consolidated Financial Statements (cont.)

## Income tax

The Group's accounting policy for taxation requires judgments as to the differences between tax and accounting treatments of income and costs recognized in the Consolidated Statement of Profit or Loss and Other Comprehensive Income. Judgment is also required in assessing whether deferred tax assets and liabilities are recognized in the statement of financial position and if accumulated income tax losses can be used to offset potential future tax profits.

## Functional currency

Effective January 1, 2021 the Group's functional currency changed from Australian dollars to US dollars as disclosed in Note 3.

The Group's assets, liabilities and equity which were previously denominated in Australian dollars were translated into US dollars on the date the functional currency changed.

Significant judgment is required in determining the currency of the primary economic environment in which the Group operates, which requires an evaluation of various indicators related to the Group's underlying transactions, events and conditions as they relate to generating and expending cash.

## 4.2 Key sources of estimation uncertainty

### Development Funding – Financial liability

The Group evaluated the Financing Agreement and determined it to be a research and development funding arrangement with the characteristics of a debt instrument, as the transfer of financial risk to Launch Tx was not considered substantive and genuine. Accordingly, the Group has recorded payments received under the Financing Agreement as part of a development financing liability in its consolidated balance sheet. The Group measures the overall development financing liability at amortized cost based on the estimated timing of regulatory approval and attainment of certain sales milestones and the contractual success fee payments expected to be due therefrom, as discounted using an imputed interest rate. The development financing liability will be accreted as interest expense to its expected future repayment amount over the expected life of the agreement using the effective interest rate method. If the dates are delayed from those used at reporting date, it is expected that a fair value adjustment will result in a non-cash gain. If the timelines for approval and launch are accelerated, the Group would anticipate a fair value adjustment resulting in a non-cash charge to be recognized in the Consolidated Statement of Profit or Loss.

### 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 35. 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. Should one or more of the assumptions and estimates used in estimating the fair value of share-based payments change, this could have a material impact on the amounts recognized in equity and employee-related expenses.

## 5. Application of new and revised Accounting Standards

### New and amended Accounting Standards that are 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.

Their adoption has not had any material impact on the disclosures or on the amounts reported in these financial statements.

## Notes to the Consolidated Financial Statements (cont.)

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

Certain new accounting standard and interpretations have been published that are not mandatory for June 30, 2023 reporting periods and have not been early adopted by the Company.

The new and revised Accounting Standards, Interpretations and amendments listed above are not expected to have a material impact on the amounts recognized or disclosures included in the Group's financial statements.

### 6. Segment information

The Group operates in one industry and two geographical areas, those being the biotechnology and healthcare industry and Australia and US, respectively.

The Group is focused primarily on developing a novel therapy for the treatment of highly prevalent and progressive retinal 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 for the purpose of resources allocation and performance assessment is the same as the information presented in the consolidated financial statements.

The Group's only revenue stream in the current and prior financial years is royalty income generated from licenses granted in respect of the Group's intellectual property that are unrelated to the Group's core business and the development of Sozinibercept OPT-302 and that are not under development. These licenses are primarily used by third-party licensees for research purposes. All of the royalty income of \$108,406 (2022: \$90,683) was generated from customers based outside of Australia. The Group does not have any major customers. All equipment is located in Australia and United States.

### 7. Revenue

	2023 US\$	2022 US\$
Sales-based royalties	108,406	90,683
<b>Total revenue</b>	<b>108,406</b>	<b>90,683</b>

### 8. Other income

	2023 US\$	2022 US\$
Grant and other income	276,869	108,322
<b>Total other income</b>	<b>276,869</b>	<b>108,322</b>

### 9. Research and development expenses

	2023 US\$	2022 US\$
Research project costs <sup>1</sup>	122,128,314	78,654,217
<b>Total research and development expenses</b>	<b>122,128,314</b>	<b>78,654,217</b>

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

## Notes to the Consolidated Financial Statements (cont.)

### 10. Expenses

	2023 US\$	2022 US\$
<b>Administrative expenses</b>		
Employee expenses:		
Salaries and fees	6,274,560	2,931,243
Cash bonuses	1,265,944	376,649
Superannuation	287,396	171,899
Share-based payments expense	5,834,686	5,251,572
<b>Total employee benefits expense</b>	<b>13,662,586</b>	<b>8,731,363</b>
Other expenses:		
Insurance	2,551,768	4,205,106
Investor relations costs	451,378	328,026
Audit and accounting	337,038	496,652
Travel expenses	580,644	13,616
Payroll tax	340,003	172,884
Legal fees	1,330,054	1,252,014
Advisory fees <sup>1</sup>	6,084,005	156,978
Consultancy costs	1,389,048	1,619,824
Other expenses	1,288,179	867,405
<b>Total other expenses</b>	<b>14,352,117</b>	<b>9,112,505</b>
Depreciation of:		
Equipment and furniture	17,000	11,917
Right-of-use asset	84,226	66,465
<b>Total depreciation expense</b>	<b>101,226</b>	<b>78,382</b>
Loss on disposal of non-current assets	-	169
<b>Total administrative expenses</b>	<b>28,115,929</b>	<b>17,922,419</b>

1. Advisory fees relates to a market assessment of potential financing alternatives and solutions.

## Notes to the Consolidated Financial Statements (cont.)

### 11. Finance income

	2023 US\$	2022 US\$
Interest income	3,227,496	235,468
	<b>3,227,496</b>	<b>235,468</b>

### 12. Interest expense on DFA

	2023 US\$	2022 US\$
Interest expense on DFA	13,462,160	-
	<b>13,462,160</b>	<b>-</b>

The interest expense on DFA is non-cash interest at the imputed rate of 23.82%.

### 13. Fair value adjustment gain on DFA

	2023 US\$	2022 US\$
Fair value adjustment gain on DFA	12,302,160	-
	<b>12,302,160</b>	<b>-</b>

There are several factors that could affect the estimated timing of regulatory approval and attainment of sales milestones, some of which are not entirely within the Group's control. Therefore, at each reporting date, the Group reassesses the estimated timing of regulatory approval and attainment of sales milestones and the expected fixed and variable contractual success fee payments due therefrom. If the timing and/or amount of such expected payments is materially different from the estimates used on the initial recognition date, the Group will adjust the accretion of the development financing liability using the previously determined imputed interest rate.

At June 30, 2023 the Group performed a fair value adjustment of the carrying amount of the Financial Liability. The expected timeline for approval and commercial launch have been delayed by twelve months, thus extending date of expected repayments. As the Group has more time to repay the amounts owed, the carrying value of the Financial Liability at June 30, 2023 was adjusted downward to reflect this delay. The fair value adjustment resulted in a non-cash gain on revaluation of \$12.3 million. This change is recorded on the Profit or Loss statement as an unrealized fair value adjustment gain on the DFA. The Group will continue to accrete non-cash interest at the imputed rate of 23.82%. Refer to Note 25.

At every reporting period, the Group will review the expected approval and commercial launch dates. If the dates are delayed from those used at June 30, 2023, it is expected that a fair value adjustment will result in another non-cash gain. If the timelines for approval and launch are accelerated, the Group would anticipate a fair value adjustment resulting in a non-cash charge to be recognized on the Profit or Loss statement.

## Notes to the Consolidated Financial Statements (cont.)

### 14. Net foreign exchange loss

	2023 US\$	2022 US\$
Net foreign exchange losses	(489,137)	(2,813,993)
	<b>(489,137)</b>	<b>(2,813,993)</b>

Exchange differences arising on the translation of monetary items are recognized in the Statement of Profit or Loss and other Comprehensive Income.

### 15. Income tax

	2023 US\$	2022 US\$
<b>(a) Income tax benefit</b>		
The major components of income tax benefit are:		
Statement of Profit or Loss and Other Comprehensive Income		
Current tax		
Current income tax credit	5,926,350	6,299,286
	5,926,350	6,299,286
Deferred tax		
In respect of the current year	-	-
<b>Total income tax benefit recognized in the Statement of Profit or Loss and Other Comprehensive Income</b>	<b>5,926,350</b>	<b>6,299,286</b>
<b>(b) Current tax receivable</b>		
Research and Development Tax Incentive Credit receivable	5,926,350	6,299,286

## Notes to the Consolidated Financial Statements (cont.)

### (c) Numerical reconciliation between aggregate income tax benefit recognized in the Statement of Profit or Loss and Other Comprehensive Income and benefit calculated per the statutory income tax rate.

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

	2023 US\$	2022 US\$
Accounting loss before tax	(148,447,435)	(99,116,657)
At the Company's statutory income tax rate of 30% (2022: 30%)	44,534,230	29,734,997
R&D tax incentive on eligible expenses	5,926,350	6,299,286
Non-deductible R&D expenditure	(4,087,138)	(4,344,335)
Other non-deductible expenses – share-based payment expense	(1,750,406)	(1,575,472)
Amount of temporary differences and carried forward tax losses not recognized	(38,696,687)	(23,815,190)
Income tax benefit reported in the Statement of Profit or Loss and Other Comprehensive Income	5,926,350	6,299,286

### (d) Recognized deferred tax assets and liabilities in statement of financial position

Deferred income tax at June 30 relates to the following:

Deferred tax liabilities:

Interest and royalty income receivable (future assessable income)	(44,785)	(17,085)
	(44,785)	(17,085)

Deferred tax assets related to temporary differences:

Recognition of tax losses	–	–
Accrued expenses and other liabilities	200,536	198,607
Employee provisions	161,006	161,159
Other miscellaneous items	270,721	306,531
	632,263	666,297
Net deferred tax assets	587,478	649,212
Less: temporary differences not recognized	(587,478)	(649,212)
Net deferred tax recognized in the statement of financial position	–	–

### (e) Unrecognized temporary differences

Temporary differences with respect to deferred tax assets associated with intellectual property and other miscellaneous items which have a low probability of realization are unrecognized. These amounted to \$nil at year end (2022: \$nil).

## Notes to the Consolidated Financial Statements (cont.)

### (f) Carry forward unrecognized tax losses

The Group had income tax losses of \$67,878,759 and capital losses of \$412,122 at year end (2022: income tax losses of \$37,717,792 and capital losses of \$412,122) for which no deferred tax asset is recognized on the statement of financial position as they are currently not considered probable of realization. These tax losses are available indefinitely for offset against future assessable income subject to continuing to meet relevant statutory tests.

### (g) Franking credit balance

Franking credits are a type of tax credit in Australia that is available to the Group's shareholder to reduce double taxation on any dividends paid by the Group. The franking account balance at the end of the financial year at 30% is A\$227,371 (2022: A\$227,371), which represents the amount of franking credits available for the subsequent financial year.

Franking credits are not recognized in the consolidated statement of financial position.

## 16. Earnings per share

	2023 US\$	2022 US\$
The following reflects the income used in the basic and diluted earnings per share computations:		
<b>(a) Earnings used in calculating earnings per share</b>		
Net loss attributable to ordinary equity holders of the parent	(142,521,085)	(92,817,371)
<b>(b) Weighted average number of shares</b>		
Weighted average number of ordinary shares on issue for basic earnings per share	442,637,406	351,560,199
Effect of dilution:		
Share options	–	–
Weighted average number of ordinary shares adjusted for the effect of dilution	442,637,406	351,560,199
Loss per share (basic and diluted in cents)	(32.20)	(26.40)

On August 24 and 28, 2023 the Company announced a capital raising which will involved 195,647,457 ordinary shares and options that represent potential ordinary shares of 97,823,728 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. There is no impact on the current basic and diluted earnings per share.

Diluted earnings per share is calculated as net loss divided by the weighted average number of ordinary shares and dilutive potential ordinary shares. Options granted under the Long-Term Incentive (LTIP) and Non-Executive Director Share and Option (NED Plan) plans would generally be included in the calculation due to the conditions of the issuance being satisfied. As the Group is in a loss position, the options are anti-dilutive and, accordingly, the basic loss per share is the same as the diluted loss per share.

## Notes to the Consolidated Financial Statements (cont.)

A total number of 25,450,000 options/rights outstanding at June 30, 2023 (2022: 22,988,000) and 1,505,000 ADS options that represent 8 ordinary shares for each ADS held (2022: 925,000) were anti-dilutive and were therefore excluded from the weighted average number of ordinary shares for the purpose of diluted earnings per share. As the Group is in a loss position, the options are anti-dilutive and, accordingly, the basic loss per share is the same as the diluted loss per share. These options related to the following option plans:

	2023 No.	2022 No.
NED Plan	16,500,000	14,000,000
LTIP	6,050,000	7,388,000
	<b>22,550,000</b>	<b>21,388,000</b>

### Performance Rights

These rights related to the following option plans:

	2023 No.	2022 No.
NED Plan	650,000	–
LTIP	2,250,000	1,600,000
	<b>2,900,000</b>	<b>1,600,000</b>

### ADS options

These rights related to the following option plans:

	2023 No.	2022 No.
NED Plan	–	–
LTIP	1,505,000	925,000
	<b>1,505,000</b>	<b>925,000</b>

As at June 30, 2023, 10,842,234 outstanding options and rights were exercisable as of that date (2022: 12,857,589).

As at June 30, 2023, 250,000 (2022: \$nil) outstanding ADS options were exercisable as of that date.



## Notes to the Consolidated Financial Statements (cont.)

### 17. Current assets – cash and cash equivalents

	2023 US\$	2022 US\$
Cash at bank and in hand	12,067,158	11,853,883
Short-term deposits	77,121,555	32,777,410
<b>Total cash and cash equivalents</b>	<b>89,188,713</b>	<b>44,631,293</b>

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 two major Australian banks 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 4.67% (2022: 0.43%).

### 18. Current assets – receivables

	2023 US\$	2022 US\$
Interest receivable	162,853	56,952
GST receivable	325,474	157,060
Other receivable	148,237	43,656
<b>Total current receivables</b>	<b>636,564</b>	<b>257,668</b>

The GST and other receivables are non-interest bearing. There were no receivables with a material expected credit loss recorded during the financial year (2022: \$nil).

### 19. Current assets – prepayments

	2023 US\$	2022 US\$
R&D Contract Research Organization	1,693,964	7,428,599
Insurance	717,064	1,086,847
Other prepayments	223,643	204,749
<b>Total current prepayments</b>	<b>2,634,671</b>	<b>8,720,195</b>

The R&D Contract Research Organization prepayment consists of prepayments on the Phase 3 clinical trial for OPT-302 in order to secure sites across the world and start patient recruitment. These prepayments covered the initial start-up of the Phase 3 clinical trials and other key milestones and are expected to be consumed within the next 12 months. The insurance amount relates to specific Phase 3 Clinical trial insurance in place for various sites around the world covering periods to 2024. The non-current portion of the prepayments are recorded as non-current assets. Refer to Note 21.

## Notes to the Consolidated Financial Statements (cont.)

### 20. Non-current assets – right-of-use assets

The Group has a three-year lease contract for its head office premises in Melbourne, Australia which commenced on July 15, 2022. The agreement does not contain any extension options. The carrying amount of the lease at June 30, 2023 is as follows:

	2023 US\$	2022 US\$
Right-of-use asset cost		
Opening balance as at July 1	281,554	281,554
Additions	252,677	-
	<b>534,231</b>	<b>281,554</b>
Right-of-use asset depreciation		
Opening balance as at July 1	(281,554)	(187,702)
Charge to the period	(84,226)	(93,852)
	<b>(365,780)</b>	<b>(281,554)</b>
<b>Net carrying amount at June 30</b>	<b>168,451</b>	<b>-</b>

### 21. Non-current assets – prepayments

	2023 US\$	2022 US\$
Insurance	53,535	110,295
<b>Total non-current prepayments</b>	<b>53,535</b>	<b>110,295</b>

The non-current prepayment amount relates to specific Phase 3 Clinical trial insurance in place for various sites around the world covering periods to 2024.

### 22. Current liabilities – payables

	2023 US\$	2022 US\$
Creditors (unsecured)	17,842,981	11,402,164
Payroll related tax liability	48,873	43,334
<b>Total current payables</b>	<b>17,891,854</b>	<b>11,445,498</b>

Creditors are non-interest bearing and are normally settled on 30 day terms.

### 23. Current liabilities – provisions

	2023 US\$	2022 US\$
Annual leave	500,361	383,220
Long service leave	252,939	212,983
<b>Total current provisions</b>	<b>753,300</b>	<b>596,203</b>

## Notes to the Consolidated Financial Statements (cont.)

### 24. Non-current liabilities – Lease Liabilities

Lease liabilities are as indicated below.

At the commencement date of the lease of its office premises, the Group recognizes lease liabilities measured at the present value of lease payments to be made over the lease term ending July 14, 2024, using an incremental borrowing rate of 3%.

	2023 US\$	2022 US\$
Carrying amount at July 1	–	112,965
New lease	252,677	–
Payments	(70,966)	(112,965)
Carrying amount at June 30	<b>181,711</b>	–
Maturity analysis:		
Year 1	102,806	–
Year 2	84,226	–
	<b>187,032</b>	–
Less: unearned interest	(5,321)	–
	<b>181,711</b>	–
Analyzed into:		
Current portion	97,485	–
Non-current portion	84,226	–
	<b>181,711</b>	–
	2023 US\$	2022 US\$
Amounts recognized in profit or loss:		
Depreciation expense of right-of-use asset	84,226	66,465
Lease finance costs	5,321	5,920
Expense relation to leases of low value assets	2,101	7,376
	<b>91,648</b>	<b>79,761</b>

## Notes to the Consolidated Financial Statements (cont.)

### 25. Non-current liabilities – financial liabilities

	2023 US\$	2022 US\$
Carrying amount at July 1	–	–
Funding at fair value	84,500,000	–
Interest expense on DFA	13,462,160	–
Fair value gain on DFA	(12,302,160)	–
<b>Total financial liabilities</b>	<b>85,660,000</b>	<b>–</b>

Pursuant to the DFA, Launch Tx has committed to provide Opthea US\$120 million in funding which may be increased up to US\$170 million at their option, of which US\$50 million (net of US\$0.5 million of funding costs) was paid in September 2022. Opthea received the proceeds from the first two tranches of the DFA, with the remainder being funded in a third tranche, to be paid on or before December 31, 2023. Pursuant to the DFA, Opthea is required to use commercially reasonable efforts to develop Sozinibercept for the treatment of wet AMD in accordance with the DFA, including pursuant to certain development timelines set forth therein. The DFA contains terms that require compliance by the Company to maintain a minimum cash balance and to provide a notice to Ocelot in the event it anticipates that it does not have sufficient cash to fund its operations for the next six months.

In return, Opthea will pay to Launch Tx (1) upon the first to occur of regulatory approval of Sozinibercept (OPT-302) for the treatment of wet AMD in the United States, United Kingdom or European Union ("Regulatory Approval"), fixed payments equal to a total of approximately two times the funding provided, consisting of seven payments, with the first payment due shortly after Regulatory Approval and the remaining six annual payments payable over a six-year period thereafter, and (2) variable payments equal to 7% of net sales of sozinibercept for the treatment of wet AMD for each calendar quarter. The fixed and variable payment obligation discharge once Launch Tx has received a total of four times their investment.

In certain instances which may result upon the termination of the Funding Agreement, we will be obligated to pay Investor several multiples of the amounts paid to us under the Funding Agreement. The Group remains in compliance with the DFA and no such instances has occurred.

The Group evaluated the Financing Agreement and determined it to be a research and development funding arrangement with the characteristics of a debt instrument, as the transfer of financial risk to Launch Tx was not considered substantive and genuine. Accordingly, the Company has recorded payments received under the Financing Agreement as part of a development financing liability in its consolidated balance sheets. The Group accounts for the overall development financing liability at amortized cost based on the estimated timing of regulatory approval and attainment of certain sales milestones and the contractual success fee payments expected to be due therefrom, as discounted using an imputed interest rate. The development financing liability will be accreted as interest expense to its expected future repayment amount over the expected life of the agreement using the effective interest rate method. Certain legal and financial advisory fees incurred specifically to complete the Financing Agreement were capitalized and recorded as a reduction to the carrying amount of the development financing liability and will also be amortized to interest expense using the effective interest method.

Pursuant to the Financing Agreement, Opthea granted Launch Tx a security interest in all its assets (other than intellectual property not related to Sozinibercept (OPT-302)), provided that the Group is permitted to incur certain indebtedness. The security interest will terminate when the Group has paid Launch Tx of the funding provided or upon certain terminations of the Financing Agreement.

There are several factors that could affect the estimated timing of regulatory approval and attainment of sales milestones, some of which are not entirely within the Group's control. Therefore, at each reporting date, the Group reassesses the estimated timing of regulatory approval and attainment of sales milestones and the expected contractual success fee payments due therefrom. If the timing and/or amount of such expected payments is materially different than original estimates, the Group will prospectively adjust the accretion of the development financing liability and the imputed interest rate. Refer to Note 13.

As of June 30, 2023, the development financing liability was classified as a long-term liability, as the Group expects the related repayments to take place between 2027 and 2032 for purposes of the model used to calculate its carrying value. The imputed interest rate on the unamortized portion of the development financing liability was approximately 23.82%.

## Notes to the Consolidated Financial Statements (cont.)

### 26. Non-current liabilities – provisions

	2023 US\$	2022 US\$
Long service leave	7,631	27,974
	<b>7,631</b>	<b>27,974</b>

### 27. Contributed Equity

	2023 US\$	2022 US\$
<b>(a) Ordinary shares</b>		
Issued and fully paid at June 30	320,883,551	235,277,217
Movement in ordinary shares:		
Opening balance	235,277,217	234,147,526
Issue of shares on exercise of options granted under the LTIP	3,790,978	1,129,691
Issue of shares net of issuance cost \$	81,815,357	–
	<b>320,883,552</b>	<b>235,277,217</b>
<b>Ordinary shares on issue:</b>	<b>No:</b>	<b>No:</b>
Opening balance	352,152,542	351,003,541
Issue of shares on exercise of options granted under the LTIP	2,387,826	1,149,001
Issue of shares	112,619,066	–
	<b>467,159,434</b>	<b>352,152,542</b>

Fully paid ordinary shares carry one vote per share and carry the right to dividends. No cash dividends have been paid, declared, or recommended during or since the end of the financial year by the Company. Issued capital at June 30, 2023 amounted to \$320,883,552 (467,159,434 fully paid ordinary shares) net of share issue costs and tax. During the year ended June 30, 2023 the Company issued 112,619,066 ordinary shares for net proceeds of \$81,815,357 via a placement in August/September 2022.

At June 30, 2023, the Company had 7,250,000 Non-Executive Director options that remain unexercised with expiry of October 2024 for 3,000,000 options, January 2025 for 2,250,000 options, October 2025 for 1,000,000 options and April 2026 for 1,000,000 options.

At June 30, 2022, the Company had 7,500,000 Non-Executive Director options that remain unexercised with expiry of November 2022 for 3,000,000, October 2024 for 2,000,000 options, January 2025 for 1,500,000 options, October 2025 for 500,000 options and April 2026 for 500,000 options.

#### (b) Options granted to directors and employees

The Company has two share-based payment schemes, the Long-Term Incentive Plan (LTIP) and Non-Executive Director Share and Option Plan. Options to subscribe for the Company's shares have been granted under these plans to certain employees and directors.

The Company granted 10,050,000 options/rights over ordinary shares and 755,000 ADS options under these plans during the year ended June 30, 2023 (Note 35). These options/rights had a weighted average fair value at grant date of \$1.62 per option. During the year ended June 30, 2023, 6,613,000 options granted under the LTIP and NED Plan were exercised for \$3,790,977 (\$1,040,718 for cash and \$2,750,258 via cashless conversion) with 2,387,826 ordinary shares issued.

## Notes to the Consolidated Financial Statements (cont.)

The Company granted 8,400,000 options/rights over ordinary shares and 925,000 ADS options under these plans during the year ended June 30, 2022 (Note 35). These options/rights had a weighted average fair value at grant date of \$0.781 per option. During the year ended June 30, 2022, 2,056,000 options granted under the LTIP and NED Plan were exercised for \$1,129,691 (\$257,175 for cash and \$872,516 via cashless conversion) with 1,149,001 ordinary shares issued.

### (c) 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. The Group only commits to significant R&D expenditure when this is fully funded either by existing funds or further equity raises.

## 28. Accumulated losses and reserves

	2023 US\$	2022 US\$
<b>(a) Movements in accumulated losses were as follows:</b>		
Balance at July 1	(216,941,353)	(124,123,982)
Net loss for the period	(142,571,085)	(92,817,371)
Balance at June 30	(359,462,438)	(216,941,353)
<b>(b) Reserves</b>		
Fair value of investments reserve (i)	1,085,411	1,085,411
Share-based payments reserve (ii)	11,551,134	8,466,706
Foreign translation reserve (iii)	20,089,163	20,089,163
Total reserves	32,725,708	29,641,280
<b>(i) Movement in fair value of investments reserve:</b>		
Opening balance	1,085,411	1,085,411
Closing balance	1,085,411	1,085,411
<b>(ii) Movement in share-based payments reserve:</b>		
Opening balance	8,466,706	4,087,650
Share-based payments expense	5,834,686	5,251,572
Exercise of options	(2,750,258)	(872,516)
Closing balance	11,551,134	8,466,706
<b>(iii) Movement in Foreign translation reserve:</b>		
Opening balance	20,089,163	20,089,163
Gain/loss on translation	-	-
Closing balance	20,089,163	20,089,163

## Notes to the Consolidated Financial Statements (cont.)

### (c) Nature and purpose of reserves

#### *Fair value of investments reserve*

This reserve records fair value changes on listed investments. As at June 30, 2023 no remaining investments are held by the Group. Management's accounting policy is to not reclassify the realized fair value to accumulated loss upon disposal.

#### *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.

#### *Foreign currency translation reserve*

The reserve records the value of foreign currency movements on the initial translation of financial statements from A\$ to US\$ that was completed in prior year.

## 29. Financial risk management objectives and policies

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

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 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 summarized 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 movements in accumulated losses 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 minimize the Group's exposure to fluctuations in interest rates that might impact its interest income 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 currently has borrowings under the DFA with Ocelot. (2022: \$nil). Refer to Note 25.

## Notes to the Consolidated Financial Statements (cont.)

The following sensitivity analysis (an annual effect) is based on the interest rate risk exposures at June 30, 2023 and 2022.

At June 30, 2023, 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:

Judgments of reasonably possible movements	Post-tax (loss)/profit impact	
	2023 US\$	2022 US\$
+ 0.50% (50 basis points) (2022: + 0.50%)	270,059	114,859
- 0.50% (50 basis points) (2022: - 0.50%)	(270,059)	(114,859)

The post-tax figures include an offset for unrecognized tax losses (bringing the tax effect to \$nil) for the year ended June 30, 2023 (2022: \$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) Foreign currency risk

As a result of services provided by non-related entities in Australia, Canada, United Kingdom and Europe, part of the Group's monetary 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			
	AUD2023 US\$	EURO2023 US\$	GBP2023 US\$	CAD2023 US\$
<b>2023</b>				
Financial assets				
Cash	55,307,319	-	-	-
Receivables	6,290,086	-	-	-
Financial liabilities				
Payables	(1,187,459)	(53,332)	(3,166)	(136,689)
Other financial liabilities	-	-	-	-
Net exposure	60,409,946	(53,332)	(3,166)	(136,689)
<b>2022</b>				
Financial assets				
Cash	26,697,582	-	-	-
Receivables	7,827,565	-	-	-
Financial liabilities				
Payables	(1,213,469)	(435,698)	(3,037)	(13,419)
Other financial liabilities	-	-	-	-
Net exposure	33,311,678	(435,698)	(3,037)	(13,419)



## Notes to the Consolidated Financial Statements (cont.)

The following sensitivity is based on the foreign currency risk exposures in existence at June 30, 2023 and 2022.

At June 30, 2023 and 2022, had the United States dollar moved with all other variables held constant, post-tax (loss) profit and equity would have been affected as illustrated in the table below:

Judgments of reasonably possible movements	Post-tax (loss)/profit impact	
	2023 US\$	2022 US\$
Consolidated		
AUD/USD +10% (2022: +10%)	(3,847,285)	(2,119,834)
AUD/USD -10% (2022: -10%)	4,702,237	2,590,908

The reasonably possible movements at June 30, 2023 are higher than at June 30, 2022 due mainly to the net exposure to the Australian dollar due to cash at bank deposits. 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 10% was calculated by taking the currency spot rates as at balance date, moving these by 10% and then re-converting the currencies into US 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.

### (iii) Credit risk

Credit risk is associated with those financial assets of the Group which comprise cash and cash equivalents and receivables. 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 recognized Australian banks.

### (iv) 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 manages liquidity risk by maintaining adequate reserves and by 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. With the funding agreement that was entered on August 12, 2022 the Group may incur a total payment equal to approximately four times the funding provided, consisting of seven payments, with the first payment due shortly after Regulatory Approval and the remaining six payments payable over a six-year period thereafter, and variable payments equal to 7% of net sales of Sozinibercept (OPT-302) for the treatment of wet AMD for each calendar quarter.

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

## Notes to the Consolidated Financial Statements (cont.)

### 30. Related party disclosures

#### (a) Subsidiaries

Name of company	Parent equity % equity interest	
	2023%	2022%
Vegenics Pty Ltd <sup>1</sup>	100	100
Opthea US Inc <sup>2</sup>	100	100

1. Opthea Limited is the ultimate parent entity. Vegenics Pty Ltd is incorporated in Australia and has the same financial year as Opthea Limited.
2. Opthea Limited is the ultimate parent entity. Opthea US was incorporated in the United States in May 2021 and has the same financial year as Opthea Limited.

#### (b) Transactions with related parties

Balances and transactions between the Company and its subsidiaries, which are related parties have been eliminated on consolidation and are not disclosed in this note. Transactions between the Group and its associates are disclosed below:

- With the appointment of Anshul Thakral (who is the CEO of Launch and Operation Executive of Carlyle) on June 7, 2023, as a Director of Opthea, resulting in Launch, Ocelot and Carlyle being related parties of Opthea.

#### Trading transactions

During the year, group entities entered into the following transactions with related parties who are not members of the Group.

	Consolidated Purchase of Services	
	2023	2022
Launch Tx – Ocelot	–	–
Launch	900,000	–

Purchase of services assisting Opthea with the management and oversight of trials under the Service Agreement with Launch Tx.

	Consolidated Amounts owed to related parties	
	2023	2022
Launch Tx – Ocelot	85,660,000	–
Launch	–	–

Amounts owed to Ocelot relate to the Development Funding agreement and carry an effective interest rate of 23.82% (refer to Note 25).

## Notes to the Consolidated Financial Statements (cont.)

### 31. Cash flow statement reconciliation

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

	2023 US\$	2022 US\$
Cash at bank and in hand (Note 17)	89,188,713	44,631,293
	89,188,713	44,631,293

#### (b) Reconciliation of net loss after tax to net cash flows from operations

Net loss for the year	(142,521,085)	(92,817,371)
Adjustments for:		
Income tax benefit recognized in profit or loss	(5,926,350)	(6,299,286)
Net loss on disposal of non-current assets	-	169
Depreciation of non-current assets	17,001	11,917
Depreciation of right-of-use asset	84,226	66,465
Share-based payments expense	5,834,685	5,251,572
Interest expense on DFA	13,462,160	-
Fair value gain on DFA	(12,302,160)	-
Net foreign exchange differences	489,137	2,813,993
	1,658,699	1,844,830
Changes in working capital:		
Payables	7,296,785	8,511,607
Receivables	378,896	307,618
Prepayments	6,142,284	5,730,207
Provisions	136,755	115,259
Net cash flows used in operating activities before tax	(126,907,665)	(76,307,850)
R&D tax incentive received	6,299,286	4,972,898
<b>Net cash flows used in operating activities</b>	<b>(120,608,379)</b>	<b>(71,334,952)</b>

## Notes to the Consolidated Financial Statements (cont.)

### 32. Commitments

#### (i) 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 3 wet AMD clinical trial and the clinical grade manufacture of OPT-302. Expenditure commitments relating to these, and intellectual property license agreements are payable as follows:

	2023 US\$	2022 US\$
Within one year	12,632,801	39,947,900
After one year but not more than five years	12,302,260	8,007,202
After more than five years	30,000	45,000
	24,965,061	48,000,102

Currently, the biggest Research contract has a 60 day termination clause and all commitments have been limited to a six month commitment.

#### (ii) Commercial commitments

The Group has entered into commercial agreements with various third parties in respect of services for preparation of OPT-302 for launch and pre-marketing phase. Expenditure commitments relating to these activities are payable as follows:

	2023 US\$	2022 US\$
Within one year	47,415	507,874
After one year but not more than five years	-	-
After more than five years	-	-
	47,415	507,874

Currently, the biggest contract has a 60 day termination clause and all commitments have been limited to a twelve month commitment.

### 33. Contingencies

The Group is 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 time-frames stipulated in the contracts, those which could become payable in less than one year total \$nil (2022: \$nil) and those which could become payable in more than one year total \$1,086,244 (2022: \$11,512,675).

Under these license/collaboration agreements, 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 June 30, 2023 in respect of a rental deposit for its office premises of \$38,036 (2022: \$39,478).

## Notes to the Consolidated Financial Statements (cont.)

### 34. Key management personnel

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

	2023 US\$	2022 US\$
Short-term employee benefits	2,898,544	1,555,658
Post-employment benefits	137,168	56,105
Share-based payments expense	4,221,472	4,664,767
<b>Total compensation</b>	<b>7,257,184</b>	<b>6,276,530</b>

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 other than those disclosed in Note 30.

### 35. Share-based payments

#### (a) Recognized share-based payment expenses

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

	2023 US\$	2022 US\$
Expense arising from equity-settled share-based payment transactions:		
Director and employee services received	5,834,686	5,251,572

#### (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.

## Notes to the Consolidated Financial Statements (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 US\$	Exercise price US\$	Expiry date	Vesting date
LTIP – director FY2016	March 7, 2016	\$0.14	\$0.36	March 7, 2021	June 30, 2016
LTIP – director FY2019	November 29, 2018	\$0.15	\$0.625	November 29, 2022	November 29, 2019
LTIP – employee FY2016	March 31, 2016	\$0.18	\$0.37	January 1, 2022	January 1, 2017
LTIP – employee FY2018	August 23, 2017	\$0.26	\$0.92	January 1, 2023	June 30, 2018
LTIP – employee FY2019	April 3, 2019	\$0.18	\$0.608	April 3, 2023	April 3, 2021
LTIP – employee FY2022	October 19, 2021	\$0.955	\$0.00	October 18, 2031	October 19, 2021
LTIP – employee FY2022	October 19, 2021	\$0.955	\$0.00	October 18, 2031	October 19, 2022
LTIP – employee FY2022	October 19, 2021	\$0.955	\$0.00	October 18, 2031	October 19, 2023
LTIP – employee FY2022	October 19, 2021	\$0.955	\$0.00	October 18, 2031	January 31, 2023
LTIP – employee FY2022	October 19, 2021	\$0.955	\$0.00	October 18, 2031	November 30, 2022
LTIP – employee FY2022	October 19, 2021	\$0.955	\$0.00	October 18, 2031	April 30, 2023
LTIP – employee FY2022	October 19, 2021	\$0.955	\$0.00	October 18, 2031	April 30, 2023
LTIP – employee FY2022	October 19, 2021	\$0.955	\$0.00	October 18, 2031	September 30, 2024
LTIP – employee FY2022	October 19, 2021	\$0.526	\$0.948	October 18, 2025	October 19, 2021
LTIP – employee FY2022	October 19, 2021	\$0.526	\$0.948	October 18, 2025	October 19, 2022
LTIP – employee FY2022	October 19, 2021	\$0.526	\$0.948	October 18, 2025	October 19, 2023
LTIP – employee FY2022	October 19, 2021	\$0.526	\$0.948	October 18, 2025	October 19, 2024
LTIP – employee FY2022	June 6, 2022	\$0.553	\$1.46	June 5, 2032	June 6, 2022
LTIP – employee FY2022	June 6, 2022	\$0.553	\$1.46	June 5, 2032	June 6, 2023
LTIP – employee FY2022	June 6, 2022	\$0.553	\$1.46	June 5, 2032	June 6, 2024
LTIP – employee FY2022	June 6, 2022	\$0.553	\$1.46	June 5, 2032	June 6, 2025
LTIP – employee FY2023	November 16, 2022	\$0.471	\$0.658	November 16, 2032	November 16, 2025
LTIP – employee FY2023	November 16, 2022	\$0.672	\$0.00	November 16, 2032	November 16, 2025
LTIP – employee FY2023	December 13, 2022	\$0.459	\$0.644	December 13, 2023	December 13, 2033
LTIP – employee FY2023	December 13, 2022	\$0.459	\$0.644	December 13, 2024	December 13, 2033
LTIP – employee FY2023	December 13, 2022	\$0.459	\$0.644	December 13, 2025	December 13, 2033
LTIP – employee FY2023	December 13, 2022	\$0.459	\$0.644	December 13, 2026	December 13, 2033
NED Plan FY2016	March 7, 2016	\$0.14	\$0.36	March 7, 2021	June 30, 2016
NED Plan FY2019	November 29, 2018	\$0.15	\$0.625	November 29, 2022	November 29, 2019
NED Plan FY2021	October 12, 2020	\$1.05	\$3.24	October 11, 2024	October 11, 2020
NED Plan FY2021	October 12, 2020	\$1.05	\$3.24	October 11, 2024	October 11, 2021
NED Plan FY2021	October 12, 2020	\$1.05	\$3.24	October 11, 2024	October 11, 2022
NED Plan FY2021	October 12, 2020	\$1.05	\$3.24	October 11, 2024	October 11, 2023
NED Plan FY2021	October 12, 2020	\$1.24	\$2.16	October 11, 2024	October 11, 2021
NED Plan FY2021	October 12, 2020	\$1.24	\$2.16	October 11, 2024	October 11, 2022

## Notes to the Consolidated Financial Statements (cont.)

Options/Rights series	Grant date	Grant date fair value US\$	Exercise price US\$	Expiry date	Vesting date
NED Plan FY2021	October 12, 2020	\$1.24	\$2.16	October 11, 2024	October 11, 2023
NED Plan FY2021	October 12, 2020	\$1.24	\$2.16	October 11, 2024	October 11, 2024
NED Plan FY2021	January 19, 2021	\$0.88	\$1.56	January 18, 2025	January 19, 2021
NED Plan FY2021	January 19, 2021	\$0.88	\$1.56	January 18, 2025	January 19, 2022
NED Plan FY2021	January 19, 2021	\$0.88	\$1.56	January 18, 2025	January 19, 2023
NED Plan FY2021	January 19, 2021	\$0.88	\$1.56	January 18, 2025	January 19, 2024
NED Plan FY2022	October 19, 2021	\$0.526	\$0.948	October 18, 2025	October 19, 2021
NED Plan FY2022	October 19, 2021	\$0.526	\$0.948	October 18, 2025	October 19, 2022
NED Plan FY2022	October 19, 2021	\$0.526	\$0.948	October 18, 2025	October 19, 2023
NED Plan FY2022	October 19, 2021	\$0.526	\$0.948	October 18, 2025	October 19, 2024
NED Plan FY2022	April 21, 2022	\$0.397	\$0.755	April 20, 2026	April 21, 2022
NED Plan FY2022	April 21, 2022	\$0.397	\$0.755	April 20, 2026	April 21, 2023
NED Plan FY2022	April 21, 2022	\$0.397	\$0.755	April 20, 2026	April 21, 2024
NED Plan FY2022	April 21, 2022	\$0.397	\$0.755	April 20, 2026	April 21, 2025
NED Plan FY2023	November 16, 2022	\$0.469	\$0.672	November 16, 2032	November 16, 2025
NED Plan FY2023	November 16, 2022	\$0.471	\$0.658	November 16, 2032	November 16, 2025
NED Plan FY2023	November 16, 2022	\$0.672	\$0.00	November 16, 2032	November 16, 2025

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 behavioral considerations. Expected volatility is based on the historical share price volatility over the past 4 or 5 years.

	Grant date share price US\$	Exercise price US\$	Fair value per option US\$	Expected volatility	Option life	Dividend yield	Risk free interest rate	Model used
LTIP – director FY2016	\$0.28	\$0.36	\$0.14	65%	5 years	0%	2.09%	Binomial
LTIP – director FY2019	\$0.42	\$0.625	\$0.15	58%	4 years	0%	2.04%	Binomial
LTIP – employee FY2016	\$0.54	\$0.37	\$0.18	65%	5 years	0%	2.09%	Binomial
LTIP – employee FY2018	\$0.34	\$0.92	\$0.26	66%	5 years	0%	2.09%	Binomial
LTIP – employee FY2019	\$0.48	\$0.608	\$0.18	57%	4 years	0%	2.04%	Binomial
LTIP – employee FY2022	\$0.955	\$0.948	\$0.526	74.78%	4 years	0%	0.25%	Binomial
LTIP – employee FY2022	\$0.955	\$nil	\$0.955	n/a	10 years	0%	n/a	n/a
LTIP – employee FY2022	\$0.901	\$1.46	\$0.553	75%	6.5 years	0%	3.4%	Binomial
LTIP – employee FY2023	\$0.672	n/a	\$0.672	75%	10 years	0%	3.7%	Binomial
LTIP – employee FY2023	\$0.672	\$0.658	\$0.471	75%	6.5 years	0%	3.6%	Binomial

## Notes to the Consolidated Financial Statements (cont.)

	Grant date share price US\$	Exercise price US\$	Fair value per option US\$	Expected volatility	Option life	Dividend yield	Risk free interest rate	Model used
LTIP – employee FY2023	\$0.643	\$0.644	\$0.459	75%	7 years	0%	3.3%	Binomial
NED Plan FY2016	\$0.28	\$0.36	\$0.14	65%	5 years	0%	2.09%	Binomial
NED Plan FY2019	\$0.42	\$0.625	\$0.15	58%	4 years	0%	2.04%	Binomial
NED Plan FY2021	\$2.19	\$2.16	\$1.24	77.25%	4 years	0%	0.25%	Binomial
NED Plan FY2021	\$2.19	\$3.24	\$1.05	77.25%	4 years	0%	0.25%	Binomial
NED Plan FY2021	\$1.56	\$1.56	\$0.88	77.01%	4 years	0%	0.25%	Binomial
NED Plan FY2022	\$0.955	\$0.945	\$0.526	74.78%	4 years	0%	0.25%	Binomial
NED Plan FY2022	\$0.741	\$0.755	\$0.397	75%	3.5 years	0%	2.7%	Binomial
NED Plan FY2023	\$0.672	\$0.672	\$0.469	75%	6.5 years	0%	3.6%	Binomial
NED Plan FY2023	\$0.672	\$0.658	\$0.471	75%	6.5 years	0%	3.6%	Binomial
NED Plan FY2023	\$0.672	n/a	\$0.672	75%	10 years	0%	3.7%	Binomial

### Fair value of American depository shares 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 behavioral considerations. Expected volatility is based on the historical share price volatility.

	Grant date share price US\$	Exercise price US\$	Fair value per ADS options US\$	Expected volatility	ADS options life	Dividend yield	Risk free interest rate	Model used
LTIP – employee	\$7.240	\$7.625	\$4.970	75%	7 years	0%	1.4%	Binomial
LTIP – employee	\$7.500	\$7.515	\$5.228	75%	7 years	0%	1.7%	Binomial
LTIP – employee	\$5.925	\$6.009	\$4.116	75%	7 years	0%	1.7%	Binomial
LTIP – employee	\$5.915	\$6.090	\$4.171	75%	7 years	0%	2.9%	Binomial
LTIP – employee	\$7.000	\$7.116	\$4.953	75%	7 years	0%	2.9%	Binomial
LTIP – employee	\$7.309	\$7.445	\$5.175	75%	7 years	0%	3.0%	Binomial
LTIP – employee	\$5.500	\$5.522	\$3.886	75%	7 years	0%	3.4%	Binomial
LTIP – employee	\$6.600	\$6.350	\$4.718	75%	7 years	0%	2.9%	Binomial
LTIP – employee	\$4.810	\$4.850	\$3.479	75%	7 years	0%	4.3%	Binomial
LTIP – employee	\$4.850	\$5.170	\$3.457	75%	7 years	0%	4.1%	Binomial
LTIP – employee	\$4.590	\$4.929	\$3.560	75%	7 years	0%	3.6%	Binomial
LTIP – employee	\$5.450	\$5.238	\$3.935	75%	7 years	0%	3.5%	Binomial
LTIP – employee	\$5.030	\$5.151	\$3.602	75%	7 years	0%	3.8%	Binomial
LTIP – employee	\$3.360	\$3.545	\$2.384	75%	7 years	0%	3.6%	Binomial



## Notes to the Consolidated Financial Statements (cont.)

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

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

	June 30, 2023		June 30, 2022	
	Number of options and rights	Weighted average exercise price US\$	Number of options and rights	Weighted average exercise price US\$
Balance at beginning of year	22,988,000	1.16	16,644,000	1.28
Granted during the year:				
To employees and directors under the LTIP and NED Plan	10,050,000	0.58	8,400,000	0.77
Exercised during the year	(6,613,000)	0.62	(2,056,000)	0.58
Expired during the year	(975,000)	0.61	-	-
Balance at end of year	25,450,000	1.04	22,988,000	1.16
Exercisable at end of year	10,842,234	1.48	12,857,589	0.97

The share options outstanding at the end of the year had a weighted average exercise price of \$1.48 (2022: \$1.16) and a weighted average remaining contractual life of 555 days (2022: 567 days).

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

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

	June 30, 2023		June 30, 2022	
	Number of options and rights	Weighted average exercise price US\$	Number of options and rights	Weighted average exercise price US\$
Balance at beginning of year	925,000	6.75	-	-
Granted during the year:				
To employees and directors under the LTIP and NED Plan	755,000	5.07	925,000	6.75
Exercised during the year	-	-	-	-
Expired during the year	(175,000)	7.62	-	-
Balance at end of year	1,505,000	5.81	925,000	6.75
Exercisable at end of year	250,000	6.70	-	-

## Notes to the Consolidated Financial Statements (cont.)

### 36. Auditor's remuneration

The auditor of Opthea Limited is Deloitte Touche Tohmatsu.

	2023 A\$	2022 A\$
Deloitte and related networks firms:		
Audit or review of the financial report of the entity and any other entity in the consolidated group	\$357,500	\$295,000
Statutory assurance services required by legislation to be provided by the auditor	-	-
Other assurances and agreed-upon procedures under other legislation or contractual arrangements	-	171,171
	\$357,500	\$466,171

### 37. Events after the balance sheet date

On August 24, 2023, Opthea announced a A\$80 million capital raise consisting via a A\$10 million private placement ("Placement") and a A\$70 million Accelerated Non-Renounceable Entitlement Offer ("ANREO"). On August 28, 2023, Opthea announced an increase in the private placement by a further A\$10 million to increase the overall raise to A\$90 million. The proceeds from the Placement and Entitlement will be used to continue advancing the clinical development of OPT-302 for the treatment of wet Age-related Macular Degeneration (wet AMD) including to progress the Company's Phase 3 clinical trials and for general corporate purposes.

The Equity Financing of A\$90 million (approximately US\$58 million) consists of two closings, of which the first closing of A\$73 million (US\$47 million) consisting of a placement offering and an acceleration portion of an Accelerated Non-Renounceable Entitlement Offer ("ANREO") occurred on September 1, 2023. The second closing of A\$17 million (US\$11 million), representing the remaining institutional and retail portion of the ANREO, has been underwritten, is subject to customary closing conditions and settlement. The shares were issued and cash received on September 20, 2023.

Subsequent to June 30, 2023, the Group was notified that a new co-investor of Carlyle and Abingworth intends to participate in a funding under the DFA of US\$50 million to increase total DFA funding from US\$120 million to US\$170 million, which is subject to the co-investor's final due diligence and regulatory and tax approvals, appropriate documentation and compliance with closing conditions. Upon completion of the final due diligence, receipt of regulatory and tax approvals, execution of the appropriate documentation and satisfaction of the closing conditions, the Group expects to receive the additional US\$50 million. While the Group anticipates that the due diligence will be completed to the satisfaction of the co-investor, the necessary approvals will be obtained, the appropriate documentation will be executed and that all closing conditions will be satisfied, there is no assurance that the Group will ultimately receive the additional US\$50 million. If the additional US\$50 million is not received by June 30, 2024, the Group will need to raise additional funds or reduce expenditures to continue as a going concern.

On August 28, 2023 Mr Lawrence Gozlan, a director of the Company, and the Company have entered into a Consultancy Agreement of up to US\$300,000 in respect of the provision of services associated with managing, overseeing and coordinating the conduct and implementation of the Capital Raising. The consultancy agreement is effective for the financial year June 30, 2024. In the opinion of the Directors, these duties are outside the scope of the ordinary duties of a Director.

Besides the above, there are no other matters or circumstances that have arisen since the end of the reporting period, 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.

## Notes to the Consolidated Financial Statements (cont.)

### 38. 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

	2023 US\$	2022 US\$
Current assets	106,797,144	61,913,395
Non-current assets	223,420	129,015
<b>Total assets</b>	<b>107,020,564</b>	<b>62,042,410</b>
Current liabilities	(17,801,129)	(11,417,465)
Non-current liabilities	(85,751,856)	(27,974)
<b>Total liabilities</b>	<b>(103,505,597)</b>	<b>(11,445,439)</b>
<b>Net assets</b>	<b>3,514,967</b>	<b>50,596,971</b>
Issued capital	320,883,552	235,277,217
Accumulated losses	(350,198,011)	(214,377,855)
Employee equity benefits reserve	11,551,134	8,466,706
Fair value of investments reserve	1,085,411	1,085,411
Foreign currency translation reserve	20,145,492	20,145,492
<b>Total shareholders' equity</b>	<b>3,467,578</b>	<b>50,596,971</b>

#### (b) Financial performance

	Year ended June 30, 2023 US\$	Year ended June 30, 2022 US\$
Loss of the parent entity	(135,820,154)	(90,264,957)
Other comprehensive income	-	-
Total comprehensive loss of the parent entity	(135,820,154)	(90,264,957)

#### (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 June 30, 2023 (2022: \$nil).

#### (d) Parent entity contingent liabilities

The Company is 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 time-frames stipulated in the contracts, those which could become payable in less than one-year total US\$nil (2022: \$nil) and those which could become payable in more than one year total \$1,086,244 (2022: \$11,512,675).

Under these license/collaboration agreements, 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 parent entity had a bank guarantee outstanding at June 30, 2023 in respect of a rental deposit for its office premises of \$38,036 (2022: \$39,478).

# Directors' Declaration

for the year ended June 30, 2023

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

1. In the opinion of the directors:
  - a. the financial report and the notes thereto are in accordance with the *Corporations Act 2001*, including:
    - i. giving a true and fair view of the Group's financial position as at June 30, 2023 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 2 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 June 30, 2023.

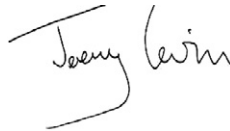
Signed in accordance with a resolution of the directors made pursuant to S.295(5) of the *Corporations Act 2001*.

On behalf of the directors:



Megan Baldwin  
CEO & Managing Director  
Opthea Limited

Melbourne  
September 28, 2023



Jeremy Levin  
Chairman  
Opthea Limited

# Auditor's Independence Declaration

# Deloitte.

Deloitte Touche Tohmatsu  
ABN 74 490 121 060

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Level 37, 10 Darcy Street  
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Australia

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

28 September 2023

Dear Directors,

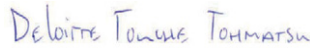
## Auditor's Independence Declaration to Opthea Limited

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 report of Opthea Limited for the year ended 30 June 2023, I declare that to the best of my knowledge and belief, there have been no contraventions of:

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

Yours faithfully



DELOITTE TOUCHE TOHMATSU



Vincent Snijders  
Partner  
Chartered Accountants

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# Independent Auditor's Report



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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 ("Opthea" or the "Company") and its subsidiaries (the "Group"), which comprises the Consolidated Statement of Financial Position as at 30 June 2023, the Consolidated Statement of Profit or Loss and other Comprehensive Income, the Consolidated Statement of Changes in Equity and the Consolidated Statement of Cash Flows for the year then ended, notes to the financial statements including a summary of significant accounting policies and the directors' declaration.

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

- (i) giving a true and fair view of the Group's financial position as at 30 June 2023 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 this report. We are independent of the Group in accordance with the auditor independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional and Ethical Standards Board's *APES 110 Code of Ethics for Professional Accountants (including Independence Standards)* (the "Code") that are relevant to our audit of the 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 the directors of the Company, would be in the same terms if given to the directors as at the time of this auditor's report.

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

#### Material Uncertainty related to Going Concern

We draw attention to Note 2 of the financial statements which indicates that the Group incurred a net loss of \$142.5 million, had a net cash outflow from operating activities of \$120.6 million during the year ended June 30, 2023, and, as of that date, the Group had an equity deficit of \$5.8 million.

As stated in Note 2, these events or conditions, along with other matters as set forth in Notes 2 and 37, indicate that a material uncertainty exists that may cast significant doubt on the Group's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

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## Independent Auditor's Report (cont.)

### Deloitte.

#### 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 for 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. In addition to the matter described in the Material Uncertainty related to Going Concern section, we have determined the matters described below to be the key audit matters to be communicated in our report.

Key Audit Matter	How the scope of our audit responded to the Key Audit Matter
<p><i>Development Funding Agreement</i></p> <p>On August 12, 2022, Opthea Limited entered into a Development Funding Agreement ("DFA") with Ocelot SPV LP (the "Investor"), an affiliate of Carlyle and Abingworth, working together with Carlyle and Abingworth's recently formed development company Launch Therapeutics, pursuant to which the Investor agrees to provide funding to Opthea to support its development of OPT-302 for the treatment of wet (neovascular) age-related macular degeneration ("wet AMD"). Pursuant to para 4.1 of the agreement, the Investor has committed to provide Opthea with US\$120 million, of which US\$50 million was paid in September 2022 and US\$35 million was paid in December 2022.</p> <p>The remainder of the funds of \$35 million will be funded in one additional tranche to be paid on or before December 31, 2023.</p> <p>Pursuant to the DFA, Opthea is required to use commercially reasonable efforts to develop OPT-302 for the treatment of wet AMD in accordance with the DFA, including pursuant to certain development timelines set forth therein.</p> <p>In return, Opthea will pay to the Investor:</p> <ul style="list-style-type: none"> <li>• Upon, the first to occur, regulatory approval of OPT-302 for the treatment of wet AMD in the United States, United Kingdom or European Union ("Regulatory Approval"), fixed payments equal to a total of approximately two times the funding provided, consisting of seven payments, with the first payment due shortly after Regulatory Approval and the remaining six annual payments payable over a six-year period thereafter, and</li> <li>• variable payments equal to 7% of net sales of OPT-302 for the treatment of wet AMD for each calendar quarter. The fixed and variable payment obligation discharge once the Investor has received a total of four times their investment.</li> </ul>	<p>In conjunction with our accounting and international tax specialists, our procedures included, but were not limited to:</p> <ul style="list-style-type: none"> <li>• Assessing the design and implementation of relevant controls in relation to management's accounting for non-routine transactions.</li> <li>• Assessing and challenging the accounting treatment of the funding arrangement in conjunction with our technical accounting specialists.</li> <li>• Reviewing and assessing management's position paper addressing the tax treatment of the funding arrangement including the use of managements and our tax specialists.</li> <li>• Assessing the accounting policy adopted by the Group to account for the DFA in accordance with IFRS 9.</li> <li>• Assessing the key assumptions adopted by management as well as the mathematical accuracy of the effective interest rate, including withholding tax considerations.</li> <li>• Assessing the fair value remeasurement of the financial liability considering the change in management's assumption around the timing of the first regulatory approval of OPT-302.</li> </ul> <p>We also assessed the adequacy of the disclosures in Note 2, 4.2, 13 and 25 to the financial statements.</p>

## Independent Auditor's Report (cont.)

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Key Audit Matter	How the scope of our audit responded to the Key Audit Matter
<p>Management exercised judgement in respect of the DFA including:</p> <ul style="list-style-type: none"> <li>• Determining whether the arrangement is a financial liability or equity.</li> <li>• Determining whether there is an embedded derivative.</li> <li>• Determining the fair value of the financial liability at initial recognition.</li> <li>• Determining the accounting policy for initial and subsequent measurement.</li> <li>• Determining the effective interest rate</li> <li>• Determining the tax considerations relating to the instrument.</li> </ul> <p>We have therefore spent significant audit effort, including the time of senior members of our audit team, in assessing the appropriateness of these assumptions.</p>	
<p><i>Research and development tax incentive</i></p> <p>The Group operates in the biotechnology market and is in the clinical research stage of developing a molecule asset, OPT-302, for the treatment of wet (neovascular) age-related macular degeneration ("wet AMD").</p> <p>The Group claims Research &amp; Development tax incentives ("R&amp;D tax incentives") provided by the Australian Government as disclosed in Note 4.1.</p> <p>For the year ended 30 June 2023, the Group has recognised an R&amp;D tax incentive receivable of \$5.9 million within the consolidated statement of financial position, with a corresponding amount recognised within income tax benefit within the consolidated statement of profit or loss and other comprehensive income.</p> <p>Management exercises significant judgement in respect of R&amp;D tax incentives claimed by the Group including:</p> <ul style="list-style-type: none"> <li>• Determining the accounting policy used in accounting for the R&amp;D tax incentive.</li> <li>• Assessing the eligibility of R&amp;D activities and costs attributed to those eligible R&amp;D activities against the rules and regulations governing the R&amp;D tax incentive.</li> <li>• Determining the estimated amounts, timing and geographical location of costs related to the projects for which R&amp;D tax incentive applications have been approved to date.</li> </ul>	<p>Our procedures included, but were not limited to:</p> <ul style="list-style-type: none"> <li>• Assessing the design and implementation of key controls in relation to R&amp;D expenditure and the preparation and review of the R&amp;D tax incentive calculation; and</li> <li>• Assessing the accounting policy adopted by the Group to account for the R&amp;D tax incentive.</li> </ul> <p>In conjunction with our R&amp;D tax specialists we performed the following procedures:</p> <ul style="list-style-type: none"> <li>• Obtaining an understanding of the rules and regulations governing R&amp;D tax incentives and the basis used by the Group to recognise the incentive.</li> <li>• Assessing the work performed by the Group's external R&amp;D tax advisors to understand the process for the preparation and review of the R&amp;D tax incentive submissions.</li> <li>• Assessing the competency and scope of the Group's external R&amp;D tax advisors.</li> <li>• Assessing management's documentation addressing how the Group's R&amp;D activities satisfy the eligibility criteria outlined in the rules and regulations governing the R&amp;D tax incentives.</li> <li>• On a sample basis, inspecting R&amp;D expenses to supporting documentation.</li> <li>• Testing on a sample basis, management's apportionment of costs to these R&amp;D activities and whether the underlying methodology used for the apportionment is consistent with the rules and regulations governing the R&amp;D tax incentive.</li> <li>• Assessing management's R&amp;D project cost claimed for tax incentives for eligible activities, including assessing the amounts claimed, timing and geographical location of the costs incurred.</li> </ul>



## Independent Auditor's Report (cont.)

### Deloitte.

Key Audit Matter	How the scope of our audit responded to the Key Audit Matter
We have therefore spent significant audit effort, including the time of senior members of our audit team, in assessing the appropriateness of these assumptions.	We also assessed the adequacy of the disclosures in Note 3, 4.1 and 15 to the financial statements.

#### Other Information

The directors are responsible for the other information. The other information comprises the information included in the Group's annual report for the year ended 30 June 2023, 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 accordingly we do not and will 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.

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

The directors of the Company 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 ability of the Group 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 Group 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 Group's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the directors.

## Independent Auditor's Report (cont.)

### Deloitte.

- 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 Group'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 Group 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.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the financial report. We are responsible for the direction, supervision and performance of the Group audit. We remain solely responsible for our audit opinion.

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.

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, actions taken to eliminate threats or safeguards applied.

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 31 to 45 of the Directors' Report for the year ended 30 June 2023.

In our opinion, the Remuneration Report of Opthea Limited, for the year ended 30 June 2023 complies with section 300A of the *Corporations Act 2001*.

##### *Responsibilities*

The directors of the Company 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



Vincent Snijders  
Partner  
Chartered Accountants  
Parramatta, 28 September 2023

## Additional Information

### Risk factors

Opthea's activities will require substantial expenditures. Opthea's losses from operations, including from clinical trial activities, and negative cash flows, raise substantial doubt about the ability for the Company to continue as a going concern without additional capital raising activities. Opthea completed the Equity Financing in two tranches, the first closing of A\$73 million (US\$47 million) which was received on September 1, 2023, and a second closing of A\$17 million (US\$11 million) on September 20, 2023. In addition, a new co-investor of Carlyle and Abingworth intends to participate in a funding under the DFA of US\$50 million to increase total DFA funding from US\$120 million to US\$170 million, which is subject to the co-investor's final due diligence and receipt of regulatory and tax approvals, appropriate documentation and compliance with closing conditions. There can be no assurance that the new co-investor of Carlyle and Abingworth will increase the funding by US\$50 million.

While Opthea expects that the proceeds of the Equity Financing of A\$90 million (approximately US\$58 million), together with additional funding expected under the DFA of US\$35 million due under the DFA by December 31, 2023, the possible increased funding under the DFA of US\$50 million and cash on hand, will provide funding to progress the activities of the Group for the next twelve months, such proceeds will not be sufficient to fully fund all anticipated costs of the Phase 3 clinical trials to top-line data. In addition, the forecast of Opthea's cash runway, following receipt of the proceeds from the Equity Financing and under the DFA, is subject to a number of assumptions, including the timing of completion of Phase 3 clinical trial patient enrollment and Clinical Research Organization ("CRO") and labor costs. Estimated patient enrollment timing used for Opthea's forecast of its cash runway is based on Opthea's monthly enrollment rates for its Phase 3 clinical trials, which timing has in the past significantly fluctuated from prior estimates, including due to factors outside Opthea's control. Opthea has in the past incurred significantly increased costs in connection with the activities conducted by third party CROs and other service providers to prepare for and progress its Phase 3 clinical trials and may continue to incur higher than expected costs for such activities in the future. CRO and related costs for the Phase 3 clinical trials have also significantly fluctuated from estimates in the past, including factors outside Opthea's control. If patient enrollment continues to be delayed in the future, or if any additional factors cause the Phase 3 clinical trials to be further delayed or more costly, including higher than expected CRO and labor costs, then the Company will need to obtain additional financing earlier than its forecast.

The third tranche of US\$35 million is due under the terms of the DFA before December 31, 2023, however, in the event the US\$35 million is not paid it would be considered a Fundamental Material Breach of the DFA by Carlyle and Abingworth. Under a Fundamental Material Breach of the DFA, Opthea has limited recourse but would have the ability to terminate the DFA by Carlyle and Abingworth. Termination by Opthea for lack of payment by Carlyle and Abingworth of the US\$35 million would relieve Opthea from any repayments under the DFA. Failure to receive the third tranche of US\$35 million or the increased funding of US\$50 million would have a negative impact on the Company's cash runway and its ability to complete enrollment in the ongoing trials.

In addition, if Opthea is unable to obtain the increased US\$50 million of funding under the DFA, then Opthea will need to seek additional capital from other sources, which may not be available on a timely basis or at all. If Opthea fails to obtain additional capital from other sources prior to top-line data for its Phase 3 clinical trials, which may not be available on a timely basis or at all, Opthea could be forced to delay, limit or terminate its operations, liquidate all or a portion of its assets and/or seek insolvency protection in the near term. Opthea's failure to raise capital prior to top-line data for its Phase 3 clinical trials, if and when needed, could delay or suspend Opthea's business strategy and could have a material adverse effect on Opthea's activities. If additional funds are raised by issuing equity, this may result in additional dilution to Opthea's shareholders. The pricing of future security issues will also depend on the results of Opthea's scientific research projects, market factors, demand for securities and the need for capital. If Opthea is unable to secure funding in the short term, there is a risk that Opthea will not be able to continue operating.

Other risk factors that are relevant to Opthea are described in the section titled "Risk Factors" in Opthea's Annual Report on Form 20-F filed with the SEC on October 28, 2022 and under "Key Risks" in Opthea's investor presentation included as an exhibit to Form 6-K furnished with the SEC on August 24, 2023, and include but are not limited to the risks that we are a clinical-stage biopharmaceutical company with no products approved for commercial sale; we have incurred net losses since our inception, we expect to incur significant losses and increasing operating losses for the foreseeable future, and we may never be profitable; we will require substantial additional capital to finance our operations, which may not be available to us on acceptable terms, or at all, as a result, we may not complete the development and commercialization of Sozinibercept (OPT-302) or develop new product candidates; failure to remain in compliance with our obligations under the Development Funding Agreement with Ocelot could lead to reduced funding under the agreement and/or the acceleration of potentially significant payments to Ocelot; and we have in the past encountered difficulties in enrolling patients in our clinical trials and if we encounter such difficulties in the future, our clinical development activities could be delayed or otherwise negatively affected.

# ASX Additional Information

## 1. Distribution of equity securities

The number of shareholders, by size of holding, of quoted fully paid ordinary shares as at August 31, 2023 is as follows:

Category	Fully paid ordinary shares	
	No. of holders	No. of shares
1 – 1,000	2,623	1,438,892
1,001 – 5,000	2,758	7,296,827
5,001 – 10,000	886	6,880,051
10,001 – 100,000	1,025	29,827,608
100,001 and Over	156	421,716,056
<b>Total</b>	<b>7,448</b>	<b>467,159,434</b>
<hr/>		
Number of shareholders holding less than a marketable parcel of shares	2,786	1,615,256

## 2. Twenty largest shareholders

The names of the 20 largest holders of quoted fully paid ordinary shares and their respective holdings at August 31, 2023 are:

Rank	Name	No. of shares	% interest
1	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	113,819,968	24.36%
2	CITICORP NOMINEES PTY LIMITED	61,449,070	13.15%
3	USB NOMINEES PTY LTD	35,562,811	7.61%
4	JP MORGAN NOMINEES AUSTRALIA PTY LIMITED	34,576,016	7.40%
5	MERRILL LYNCH (AUSTRALIA) NOMINEES PTY LIMITED	23,329,680	4.99%
6	NATIONAL NOMINEES LIMITED	22,739,390	4.87%
7	BNP PARIBAS NOMS PTY LTD <DRP	15,855,958	3.39%
8	JAGEN PTY LTD	11,581,484	2.48%
9	WARBONT NOMINEES PTY LTD <UNPAID ENTREPOT A/C>	6,875,408	1.47%
10	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED <NT-COMNWLTH SUPER CORP A/C>	5,762,622	1.23%
11	HSBC CUSTODY NOMINEES (Australia) LIMITED – A/C 2	5,519,023	1.18%
12	MS MARGARET LYNETTE HARVEY	5,268,323	1.13%
13	ARMADA TRADING PTY LIMITED	5,005,806	1.07%
14	SAFO TRADING PTY LTD	3,641,130	0.78%
15	GAJA HOLDINGS	3,207,576	0.69%
16	SAFO INVESTMENTS PTY LTD <SAFO INVESTMENTS A/C>	3,039,766	0.65%
17	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED <GSCO CUSTOMERS A/C>	3,000,000	0.64%
18	BILGOLA NOMINEES PTY LIMITED	2,934,490	0.63%
19	SUIBIAN TRADING PTY LTD	2,933,644	0.63%
20	SANDHURST TRUSTEES LTD <JMFG CONSOL A/C>	2,561,995	0.55%
<b>Totals: Top 20 holders of ordinary fully paid shares</b>		<b>368,664,160</b>	<b>78.92%</b>
<b>Total remaining holders balance</b>		<b>98,495,274</b>	<b>21.08%</b>

## ASX Additional Information (cont.)

### 3. Substantial shareholders

The following information is current at August 31, 2023 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
Regal Funds Management Pty Ltd	93,246,599
Bakers Brothers Life Sciences LP	31,627,844
USB Group AG and its related bodies corporate	33,322,088
Bank of America Corporation and its related bodies corporate	23,425,608

### 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 Directory

## Company

Opthea Limited  
ABN 32 006 340 567

## Directors

Jeremy Levin  
Non-Executive Director and Chairman

Megan Baldwin  
Managing Director and Chief Executive Officer

Lawrence Gozlan  
Non-Executive Director

Anshul Thakral  
Non-Executive Director

Daniel Spiegelman  
Non-Executive Director

Julia Haller  
Non-Executive Director

Susan Orr  
Non-Executive Director

Quinton Oswald  
Non-Executive Director

## Company Secretary

Karen Adams  
BBus, CPA GAICD,FGIA FCG

## Registered office

Level 4, 650 Chapel Street  
South Yarra, Victoria 3141

## US Office

103 Carnegie Center Boulevard,  
Suite 300, Princeton NJ, 08540

## Principal administrative office

Level 4, 650 Chapel Street  
South Yarra, Victoria 3141

[www.opthea.com](http://www.opthea.com)

Telephone: +61 (3) 9826 0399

## Bankers

Commonwealth Bank of Australia  
Melbourne, Victoria

## Auditors

### Deloitte Touche Tohmatsu

8 Parramatta Square  
Level 37, 10 Darcy Street  
Parramatta, NSW 2150  
Australia

## Solicitors

### Gilbert and Tobin

101 Collins Street  
Melbourne, Victoria 3000

### Cooley LLP

3175 Hanover Street,  
Palo Alto, CA, 94304  
USA

## Share register

### Computershare Investor Services Pty Ltd

Yarra Falls, 452 Johnston Street  
Abbotsford, Victoria 3067

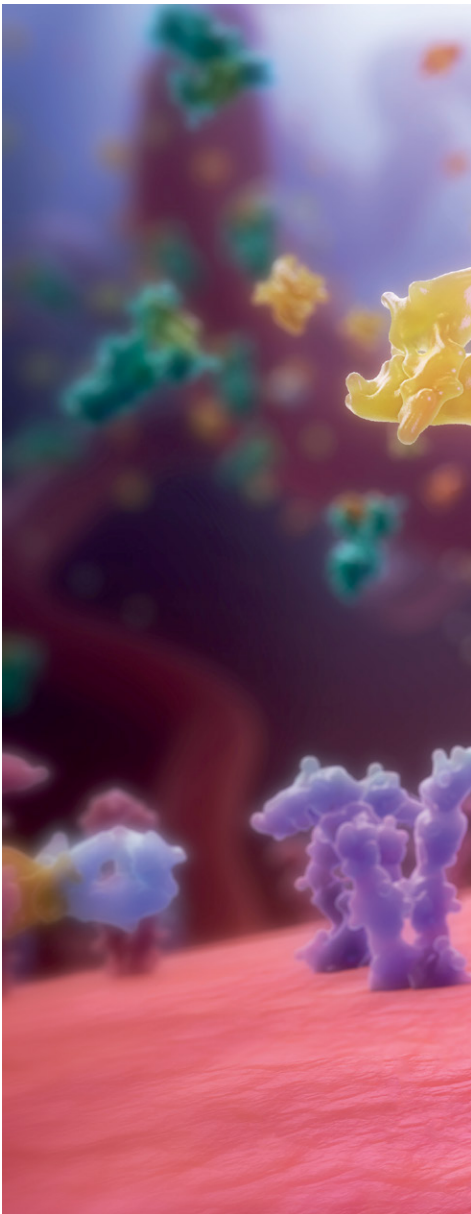
Telephone: +61 (3) 9415 4000 or  
1300 850 505 (within Australia)

## Stock exchange listing

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

Opthea Limited American Depositary Shares ("ADS") options are quoted on the National Association of Securities Dealers Automated Quotations ("NASDAQ") Stock Market (code: OPT).

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