

# Appendix 4E Preliminary Final Report

OPTHEA LIMITED ABN 32 006 340 567

#### YEAR ENDED JUNE 30, 2022 RESULTS FOR ANNOUNCEMENT TO THE MARKET

	June 30, 2022 \$	June 30, 2021 \$	Movement %
Revenues from ordinary activities	90,683	68,613	Up 32.1%
Loss from ordinary activities after tax attributable to members	(92,817,371)	(45,344,496)	Loss has increased 104.7%
Loss for the year attributable to members	(92,817,371)	(45,344,496)	Loss has increased 104.7%
NTA Backing			
Net tangible asset backing per ordinary security	0.21	0.58	

#### **Dividend distribution**

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

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



# PROGRESSING WITH A CLEAR OBJECTIVE

ANNUAL REPORT 2021 - 2022

# WHO?

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 exchange in October 2020, we are well positioned to advance our lead therapeutic candidate OPT-302 through Phase 3 clinical trials in support of future registration filings for marketing approval and commercialization.

# WHAT?

Our first-in-class novel therapeutic called 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.

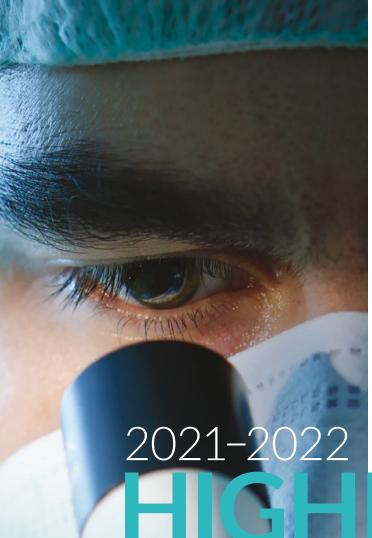
## WHY?

Millions of people around the world suffer from impaired vision as a result of diabetes and 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.

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**Continued** patient enrollment for ShORe and **COAST Phase 3 clinical trials** in the United States, and initiated patient recruitment in Europe, Canada, Asia **Pacific and Latin America Expanded our leadership** team, Board of Directors and operations in the **United States** 



# HLIGHTS

Increased our profile with the global investment and clinical ophthalmology community through participation in local and international conferences, symposia and events, including the American Society Retina Specialists (ASRS), Retina World, Angiogenesis and Association for Research in Vision and Ophthalmology (ARVO) conferences

Built on our regulatory strategy with OPT-302 granted Fast-Track Designation for wet AMD in July 2021

Strengthened Opthea's strategic position to maximize the value of OPT-302 through the announcement of a non-dilutive financing transaction for up to US\$170 million and a US\$90 million equity financing

# **OPT-302 PROGRESSING** IN GLOBAL WET AMD PHASE 3 TRIALS

Wet AMD affects over 3.5 million people in the US and Europe. OPT-302 having demonstrated meaningful, improved visual outcomes in its Phase 2b studies steps us closer to helping a large and growing population.

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

ShORe: Study of OPT-302 in combination with Ranibizumab

COAST: Combination 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 OPT-302 combination therapy for the treatment of wet AMD. Both Phase 3 studies evaluate OPT-302 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 OPT-302 combination therapy compared to standard of care anti-VEGF-A monotherapies.



activated sites and enrolled patients in the two pivotal Phase 3 clinical trials for the treatment of wet AMD

Over **170** clinical trial sites activated globally for each

Phase 3 trial

**Approximately** 

countries around the world are recruiting patients for our Phase 3 program

#### WHY OPT-302

Current standard of care treatments for wet AMD are largely limited to VEGF-A inhibitors such as ranibizumab (Lucentis®) or aflibercept (Eylea®). This is administered as an injection once or twice per month by intravitreal delivery. Though 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, they experience further vision loss after 12 months.

Recent and current clinical trials in the wet AMD landscape have focused on achieving increased durability, measured by longer treatment intervals, without aiming to improve visual outcomes. By contrast, our successfully completed Phase 2b study data has demonstrated OPT-302 combination therapy offers superior vision gains (mean BCVA gain of +3.4 letters) over the current standard of care in 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 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 at August 2022, over 150 clinical trial sites for each study have been activated in the US, Canada, Europe and Asia Pacific. When fully activated, we expect over 190 clinical trial sites to participate in each study.

Over the next 12 months, we will continue to work with a global Clinical Trial Organization to accelerate recruitment and site activations with a target completion of mid-2023.

## COMPLETING THE 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 OPT-302 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 OPT-302 combination therapy versus standard of care therapy alone. Topline data for primary analysis is expected to be reported when all patients complete the 52-week treatment period.

If the topline results at the completion of the primary efficacy phase are favorable, we intend to file for marketing approval for OPT-302 for the treatment of wet AMD in the US and EU as a priority.

#### FAST-TRACK DEVELOPMENT TIMELINE

Superior Phase 2b results led to the US FDA granting Fast-Track designation to OPT-302 as 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 Europe respectively.

## COMMERCIAL ADVANTAGES

Investigation of OPT-302 as a combination therapy with two leading standard of care treatments may position OPT-302 as a complementary treatment for administration with any VEGF-A inhibitor.





### MEET OUR CHIEF MEDICAL OFFICER

# JOEL NAOR, MD

Dr. Joel Naor, based in Palo Alto, Silicon Valley California and Opthea's Chief Medical Officer, has been involved in the field of retinal disease therapeutics "from its inception" more than 20 years ago. Dr. Naor has worked on approaches ranging from photodynamic therapy (PDT), biologics, small molecules, sustained release technologies, and stem cells.

"I worked on PDT, which was the first product – or technology – to be approved, in 2000, and I've seen retinal therapies go from nothing to a multi-billion dollar market."

"But since the first approval of the class of drugs that block VEGF-A, in 2004, we've had really very little progress in the field offering advances in patient visual functional improvements. There's been a lot of drugs, and now, there are even biosimilar anti-VEGF-A drugs, but everything that has been subsequently approved has been on the basis of being 'as-good-as,' or non-inferior to the initial anti-VEGF-A treatment approach - and none of them have been shown to improve efficacy. That was until our product OPT-302 came along with its potential to change things."

"There is definitely a sense that we're doing something very unique here at Opthea, something quite noble, in that we're working on a new mechanism of action that may improve patient outcomes, for a very important human need – vision."

"The majority of work in this field, in effect, has said to patients, 'Hey, we are going to make your life a little bit easier, you're not going to have to see the doctor as frequently, but don't expect anything more in terms of your vision or other outcomes.' However we believe OPT-302 is bringing benefit to patients by potentially improving visual outcomes. That's a huge diffentiator for Opthea, and a big motivator for employees, but also patients and physicians."

For Dr. Naor, OPT-302 potentially gets to the heart of personalized medicine. "Most of the results by which we judge drugs are based on some average that is observed in a patient population, but we know that many patients do not actually respond optimally, and patients do not respond equally. Here, we have a drug that may actually benefit a significant group of patients. I think each of us feels that it would be very satisfying to see OPT-302 through to application in patients. I've worked with companies that succeeded before, and in our world, there's nothing like that rush."



#### MEET OUR CHIEF COMMERCIAL OFFICER

# JUDITH ROBERTSON

Chief Commercial Officer Judith Robertson came to Opthea in January 2022 by a unique route; she was on the Board of Directors as a non-executive director who elected to move across to the executive team. Robertson was appointed to the Opthea Board precisely because of her 25+ years of successful track record in biopharma commercialization with companies such as Johnson & Johnson, Alcon and Novartis.

"I was only on the board of Opthea a few months and realized two things very quickly. Firstly, OPT-302 is an incredible asset that is highly differentiated in the wet AMD space and represents the only asset in the near and long-term development pipeline with the potential to address the most important unmet need in wet AMD, the need to improve visual outcomes over standard of care anti-VEGF therapy. Secondarily, there is much opportunity, from a global perspective, to increase the awareness of Opthea, OPT-302 and the inherent commercial opportunity in our lead product candidate."

"I was, and continue to be, impressed by the pioneering culture and tenacity of Opthea, a company unrelenting in their pursuit of the VEGF-C and VEGF-D pathway and unyielding in the goal to improve visual outcomes for patients suffering from wet AMD".

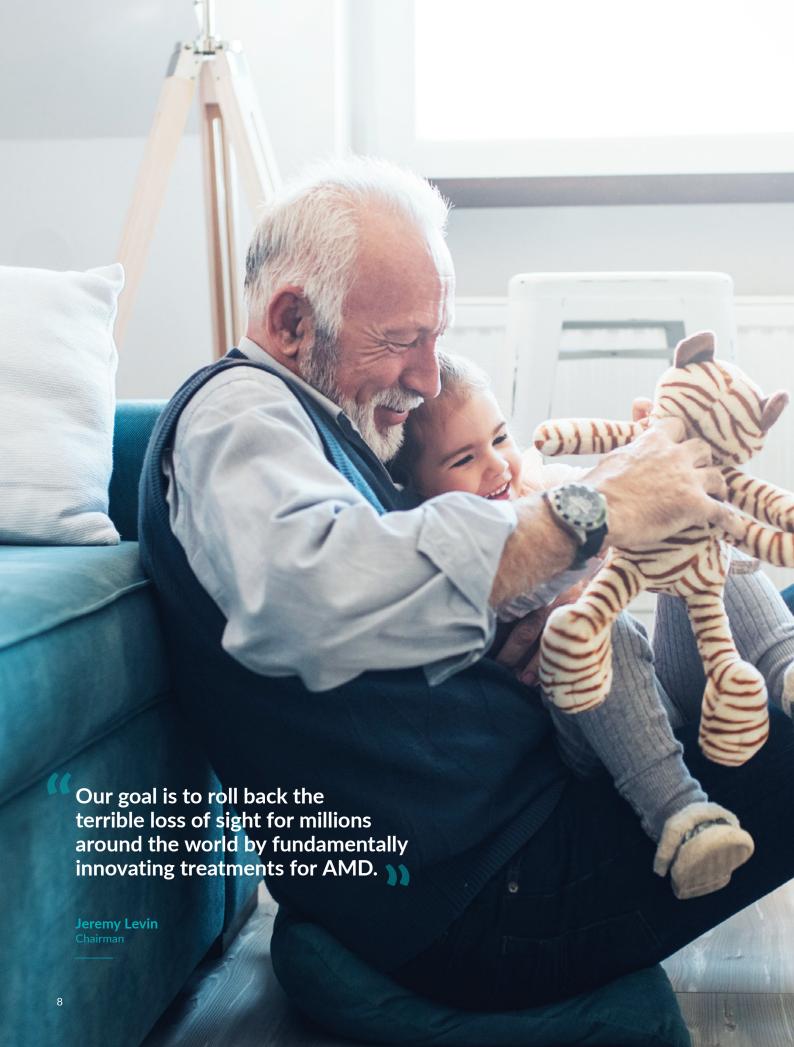
Judith Robertson's decision to join the executive management team as Chief Commercial Officer was strengthened by her conviction that she could apply her significant experience in commercialization of eye disease therapeutics to position OPT-302 as the next transformative treatment paradigm for wet AMD.

Robertson concluded with this final statement,



As Chief Commercial Officer, I recognize that with all great innovation comes great responsibility and accountability, and I intend to apply ever aspect of my acumen, experience and passion to ensuring the OPT-302 becomes a reality for wet AMD patients worldwide.







# CHAIRMAN'S REPORT

Let me start by reiterating my comments of last year and note that on behalf of the Board and management of Opthea, we send our best wishes to shareholders in the hope that they and their loved ones have passed this last year without major mishap occasioned by the pandemic. We also express our deepest sympathy to those who are amongst the millions of families who have suffered loss from COVID-19. The role of biotechnology in pushing back the depredations of the pandemic by bringing new vaccines and medicines to the battle against COVID-19 has been remarkable.

We at Opthea are proud to be part of that global innovation engine. Our goal is to roll back the terrible loss of sight for millions of people around the world by fundamentally innovating treatments for AMD. We firmly believe that by doing so, we will benefit patients, shareholders and more broadly help increase the economic health of our society as workers who might be affected can continue to live normal and productive lives.

To do this we have taken key steps. One year ago we embarked on building out our board. That has been accomplished with the addition of Mr. Quinton Oswald and Dr. Susan Orr, leaders in the fields of ophthalmology. More recently we have now established the financing to further enable us to work towards completing our Phase 3 clinical trials. Joined by world-leading investors Carlyle and its life sciences franchise Abingworth, we have secured additional capital resources to continue to tackle the remaining steps for our Phase 3 clinical trials.

Going forward, our focus will be on execution of the Phase 3 trials and laying the necessary groundwork for a commercial launch should our trials succeed. While taking these steps, we will endeavor to create better visibility for our company within the global investor and clinical ophthalmology communities.

It is notable that in the last year we have continued to progress our Phase 3 trials and expanded our management team in the US following our listing on the NASDAQ stock exchange in October 2020. We are now focused on further strengthening our management team and advancing our clinical program, while bringing to the attention of investors around the world the remarkable potential that we believe our product candidate OPT-302 holds.

As generic versions of older treatments are introduced, the market potential remains considerable for OPT-302, an investigational agent in late-stage development with the potential to improve vision outcomes over standard of care for patients with wet AMD. This excites us. We are motivated to deliver the value that we believe is inherent in our product and our approach.

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 families of those with disorders of the eye and to our shareholders.

Sincerely

Jeremy Levin Board Chairman Opthea Limited



# CEO'S RFPORT

#### Dear Shareholders

The past 12 months has seen Opthea make tremendous progress in establishing Opthea as a globally recognized, emerging biotechnology company in ophthalmology.

Our experienced management team, now based in both Australia and the United States, has grown significantly over the past year as we recognize the importance of building our profile globally with highly experienced executives who have proven track-records in late-stage clinical development and bringing therapies to market. During the year we welcomed Opthea's first Chief Medical Officer and Chief Commercial Officer, and expanded our manufacturing, clinical operations and commercial teams to advance OPT-302 through our pivotal Phase 3 trials in anticipation for potential commercialization, if approved. Aligned with the expansion of the management team, Opthea's Board was also bolstered with the addition of Mr. Quinton Oswald and Dr. Susan Orr as non-executive directors who bring a breadth of experience in leading biotechnology companies and launching commercial products for wet AMD and other ophthalmic diseases.

Whilst expanding our operations, our commitment to advancing OPT-302 has only strengthened. Wet AMD is a debilitating disease that affects central vision and consequently, greatly impacts quality of life and the ability for patients to live independently. Current standard of care treatments for wet AMD are largely limited to VEGF-A inhibitors and although they have revolutionized the treatment of wet AMD, despite receiving regular administration of this class of therapy, a majority of patients

fail to achieve sufficient vision gains to resume routine daily activities such as driving and reading. There is an urgent need for new approaches, beyond selective inhibition of VEGF-A. to improve outcomes for patients with wet AMD. OPT-302, as a VEGF-C/D inhibitor, is complementary to anti-VEGF-A treatments. Used in combination. OPT-302 achieves broad blockade of the VEGF pathway and targets important mechanisms that are associated with sub-optimal vision improvement in patients receiving standard of care treatments alone. It is this understanding of the mechanism of our treatment, OPT-302, which drives us to advance OPT-302 through the final stages of clinical development. Phase 3 clinical trials.

Our Phase 3 program has been informed greatly by the outcomes of our Phase 2b clinical trial in wet AMD that demonstrated superior vision outcomes when OPT-302 is administered in combination with standard of care anti-VEGF-A therapy. Although we have maintained many important aspects of our trial design in the Phase 3 studies, importantly the design of and our analysis plan for ShORe and COAST have been optimized based on Phase 2b outcomes to maximize probability of success and commercial opportunity for OPT-302. We are now actively recruiting patients globally for ShORe and COAST and expect to complete patient recruitment for both trials in mid calendar year 2023 and to report topline data in mid calendar year 2024. Over the next 12 months we will continue to robustly manage execution of these studies with the clear objective of bringing this important new treatment

to patients for whom there are currently limited treatment options.

Our recent announcements of an up to US\$170 million non-dilutive financing for our OPT-302 program in wet AMD, with Launch Therapeutics, a recently formed development company backed by funds managed by global investment firm Carlyle and its life sciences franchise Abingworth, together with a concurrent US\$90 million private institutional placement (with approximately US\$47.5 million subject to shareholder approval) and share purchase plan, reflect the potential of OPT-302 to change the treatment paradigm for wet AMD and the promising commercial opportunity for the asset. We expect these transactions will greatly assist Opthea in funding its pivotal Phase 3 clinical trials.

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

Thank you for your support.

of 5

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, including, but not limited to, the expected enrollment of a significant number of patients for the trials, Phase 3 registrational program and commercialization efforts for OPT-302, the expected timing of Opthea's Phase 3 program and trials, Opthea's anticipated funding needs and cash runway, including following the financing activities, Opthea's ability to meet its payment and other obligations under the financing arrangements,

including compliance with the minimum cash requirement, Opthea's ability to draw the entire US\$170 million of funding capacity in a timely manner or at all, Opthea's ability to consummate the second tranche of the private institutional placement, and Opthea's goal of building out a substantial presence in the United States. Such statements are based on Opthea's current plans, objectives, estimates, expectations, and intentions and are subject to certain risks and uncertainties, including risks and uncertainties associated with clinical trials and product development, including unexpected costs or delays in the clinical trial process, risks from the continuing COVID-19 pandemic, and the impact of general economic, industry or political conditions in Australia, the United States or

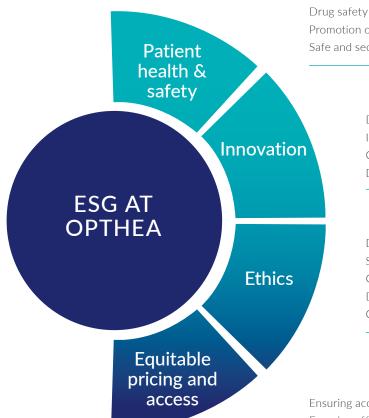
internationally. These and other risks and uncertainties are described more fully in the section titled "Risk Factors" in Opthea's Annual Report on Form 20-F filed with the SEC on October 28, 2021. If the risks materialize or assumptions prove incorrect, actual results could differ materially from the results implied by these forward-looking statements. Opthea undertakes no obligation to publicly update any forward-looking applicable law. You should not place undue reliance on these forward-looking statements as predictions of future events, which statements apply only as of the date of this announcement. Actual results could differ materially from those discussed in this report.

# ENVIRONMENTAL, SOCIAL AND GOVERNANCE AT OPTHEA

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

As a biotechnology innovator, Opthea recognizes the opportunity we have to drive positive outcomes for not only our own business but for the promotion of public health. Our approach to environmental, social and governance (ESG) pivots on how we intend to unite these positive outcomes with the growth of enterprise value by integrating ESG decision-making into all aspects of Opthea's operations.

Opthea has identified a range of key factors to serve as the foundation for a meaningful, purposeful, and practical ESG strategy. This has the potential to transform the way we discover and develop medical breakthroughs that will change the lives of our patients. We also understand the importance of setting measurable targets against which we can track our progress over time. This will ensure accountability to our stakeholders while enabling the business to celebrate and recalibrate as we continue to grow.



Drug safety
Promotion of public health
Safe and secure clinical trials



Driving enterprise value Intellectual property protection Continued innovation Diversity and inclusion



Data privacy
Supply chain transparency
Clear and accurate labeling
Dealing with medical professionals
Competitive behavior



Ensuring accessibility
Ensuring affordability and fair pricing



### Our priority issues

# Committed to low impact business operations

#### **DRUG SAFETY**

Ensuring the safety of our therapies is of critical importance to Opthea. We have protocols in place to monitor clinical trial safety, and follow strict processes in our drug supply chain. This includes maximizing transparency across supply chain and the conduct of our clinical trials, which has a wide range of benefits to our stakeholders. These range from clarity over labor practices, to environmental tracking, and serves as a measure to ensure each drug batch is tracked and secure. Monitoring the safety and efficacy of our drugs is one of the primary methods by which Opthea strives to enhance public health.

#### PATIENT PRIVACY

Standard operating procedures for clinical trial conduct and its data safety forms the backbone of its ongoing patient privacy strategy. Our process and the committee plays a key role in the oversight of patient privacy and sensitive information. Its proactivity of data privacy risk monitoring exceeds basic industry requirements, displaying an extreme aversion to potential threats or leaks. Opthea also requires internal staff to undergo data privacy training procedures.

#### INNOVATION AND IP

The development of an innovative therapy to improve patient vision is central to Opthea's enterprise value. As such, the business engages professional patent attorneys to monitor its ongoing intellectual property. Similarly, we firmly believe that fair and ethical competitive behavior is essential to a healthy commerce. As such, Opthea maintains strict corporate governance policies, in place to address this issue.

#### **BUSINESS ETHICS**

Opthea is under strict regulation regarding its ethical expectations for dealing with medical professionals, such as complete impartiality. Beyond this, Opthea is committed to accuracy and clarity over the marketing and labeling of its future products. Our corporate policy for recruitment is to hire the most appropriate individual for the role. Opthea recognizes the benefits of internal diversity, such as a wide range of opinions and backgrounds contributing to ideation, innovation, and problem-solving.

#### **ACCESS & AFFORDABILITY**

We envisage a future of sustainable healthcare solutions where all people have fair and affordable access to life-changing eye treatment. This forms a key cornerstone of our mission to enhance public health by improving the vision of our patients. Opthea will take measures to focus on affordability of its therapies. Opthea's initial research in this space has informed the company's expectations of pricing and a more detailed framework will be created once appropriate.

Opthea recognizes the threat a changing climate poses to global health and minimizes its emissions contribution wherever practicable. Our environmental footprint is inherently low, and to help maintain this we have a policy to allow employees to work from home, reducing transport emissions. We also offset our infrequent flights.

The importance Opthea places on transparency extends to our commitment to a supply chain free from human and labor rights violations. The relationships and procedures we have in place with suppliers maximize our supply chain transparency and visibility of any potential shortcomings in labor rights.

Opthea minimizes its waste generation by partnering with sustainable vendors for our medical products, encouraging the decoupling of medical treatment from plastic waste. Our office waste is managed collectively by our Melbourne office complex. A waste stream procedure is in development in advance of our products coming to market, at which point our key waste sources will be plastic needles, glass vials, and associated packaging. In addition, our products do not exacerbate the depletion of primary resources as input materials are self-regenerative. biological, and only needed in relatively small quantities.

## Directors' Report

The board of directors of Opthea Limited submits its report for the year ended June 30, 2022 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:

Jeremy Levin, Non-Executive Director and Chairman

Megan Baldwin, Managing Director and Chief Executive Officer

Susan Orr, Non-Executive Director (appointed April 21, 2022)

Michael Sistenich, Non-Executive Director

Lawrence Gozlan, Non-Executive Director

Daniel Spiegelman, Non-Executive Director

Julia Haller, Non-Executive Director

Judith Robertson, Non-Executive Director (resigned January 1, 2022)

Quinton Oswald, Non-Executive Director (appointed April 21, 2022)

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 the 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 B.A. 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**

#### B.Sc (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 OPT-302 for the treatment of wet age-related macular degeneration. Prior to joining Opthea, she was employed at Genentech (now Roche), the world leader in the field of angiogenesis-based therapies for cancer and other diseases.

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

#### MICHAEL SISTENICH

#### M.Sc

#### **Non-Executive Director**

Michael Sistenich was appointed Non-Executive Director of Opthea in November 2015 and is Chairman of the Remuneration committee. 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**

#### B.Sc. (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 leading 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**

#### B.A., 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 and a member of the board of directors 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 B.A. from Stanford University and an MBA from the Stanford Graduate School of Business.

#### DR. JULIA HALLER

#### M.D.

#### 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 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. She is a member of the National Academy of Medicine and serves on several prestigious boards including the board of the John Hopkins Medical and Surgical Association, the Association of University Professors of Ophthalmology, the College of Physicians of Philadelphia, and the Society of Heed Fellows. She is President of the Women in Medicine Legacy Foundation and a member of the National Academy of Medicine. Previously Dr. Haller was a director of Celgene Corporation and Professor of Ophthalmology, Johns Hopkins University School of Medicine, The Wilmer Eye Institute, where she directed the Retina Fellowship Training Program from 2001-2007. Dr. Haller received a B.A. 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 Biothereapeutics 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 that 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® (brolucizumab) and has been a Managing Partner at Fovenedeve 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 commercialstage 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®.

#### 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
	Lundbeck (NASDAQ)	Since 2017
Megan Baldwin	Invex Therapeutics (ASX)	Since 2020
Lawrence Gozlan	Alterity Therapeutics Limited (ASX)	Since 2011
Daniel Spiegelman	Myriad Genetics (NASDAQ)	Since 2020
	Jiya Acquisition Corp (NASDAQ)	Since 2020
	Spruce BioScience (NASDAQ)	Since 2020
Julia Haller	Eyenovia (NASDAQ)	Since 2021
	Bristol Myers Squibb (NYSE)	Since 2019

#### **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	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

#### **Share options**

As at June 30, 2022 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 2016, 2018, 2019, 2021 and 2022 financial years the Company granted 25,969,000 options, rights and ADS options to purchase ordinary shares to directors and employees under the Long Term Incentive (LTIP) and Non-Executive Director Share and Option (NED) Plans.

Grant date	Expiry date	Granted to	Exercise price	Number of options granted
March 7, 2016	March 7, 2021	Directors under the LTIP and NED plan	\$0.36	7,000,000
March 31, 2016	January 1, 2022	Employees under the LTIP	\$0.37	2,625,000
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
				32,769,000

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
				1,600,000

Grant date	Expiry date	Granted to	Exercise price	Number of ADS options
October 18, 2021	October 18, 2031	Employees under the LTIP	\$7.62	175,000
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
				925.000

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

#### **Dividends**

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

#### **Principal activities**

The principal activity of Opthea Limited is to develop and commercialize therapies primarily for eye disease. Opthea's lead asset, OPT-302, is a soluble form of VEGFR-3 in clinical development as a novel therapy for wet (neovascular) age-related macular degeneration 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 2021-2022 included progression of the Company's Phase 3 registrational trials of 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 OPT-302 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.

#### Operating and financial review

#### FINANCIAL PERFORMANCE

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

A summary of the results is as follows:

- The major expenditure of the Group has been in relation to R&D, in particular costs associated with the Phase 3 clinical trials;
- Total R&D expenditure amounted to US\$78,654,217 (2021: US\$25,891,851). 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\$14,481,116 (2021: US\$11,403,170);
- Opthea received an R&D tax incentive payment during the year of US\$4,972,898 (2021: US\$5,834,100); and
- The consolidated net loss of the Group for the year was US\$92,817,371 after an income tax benefit of US\$6,299,286 (2021: loss of US\$45,344,496 after an income tax benefit of US\$4,938,846).

#### FINANCIAL POSITION

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

- Consolidated cash balances as at June 30, 2022 amounted to US\$44,631,293 (2021: US\$118,193,177);
- Receivables of US\$6,556,954 (2021: US\$5,538,184) include the Opthea Group's expected refund of R&D tax incentives for the year to June 2021 of US\$6.299,285 (2021: US\$4,972.898):
- The Group has a net current asset surplus of US\$47.866.741 (2021: US\$135,011,031); and
- The net tangible asset backing per share as at June 30, 2022 was US\$0.21 (2021: US\$0.58); Opthea's share price was AU\$1.10 (2021: AU\$1.34).

#### **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 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 (neovascular) AMD and other retinal diseases. OPT-302 has the potential to be positioned as complementary and agnostic with any combined 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 central 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, together generated worldwide revenues in excess of US\$12 billion in 2021. 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.

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 OPT-302 is well 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 OPT-302 is a promising drug candidate with large commercial potential as it advances through the final stage of clinical development, Phase 3 pivotal studies.

#### OPT-302: 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 (PIGF). 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. OPT-302 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. OPT-302 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). OPT-302 binds or 'traps' VEGF-C and VEGF-D with high affinity, blocking the activity of both molecules.

OPT-302 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 OPT-302 with a VEGF-A inhibitor, 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. OPT-302 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 OPT-302 as a combination therapy for wet (neovascular) 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, activation of clinical trial sites in countries in various regions around the world and manufacture of OPT-302 to cGMP standards for use in the clinical trials. The Company also conducted activities to support commercialization of the product, included enhancing its presence at clinical ophthalmology conferences and symposia and representation at 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.

OPT-302 was advanced into Phase 3 pivotal trials based on clinical experience to date, which includes three completed studies: two with OPT-302 in combination with ranibizumab (Lucentis®), a VEGF-A inhibitor, in patients with wet AMD; and one with OPT-302 in combination with aflibercept (Eylea), a VEGF-A inhibitor, in patients with persistent, center involved diabetic macular edema (DME). Notably, 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.

#### OPTHEA'S PHASE 3 PIVOTAL TRIALS - SHORE AND COAST

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

- ShORe: Study of OPT-302 in combination with Ranibizumab (Study OPT-302 1004); and
- COAST: Combination OPT-302 with Aflibercept Study (Study 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 OPT-302 on a standard every four weeks dosing regimen or 2.0 mg OPT-302 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 OPT-302 on a standard every four weeks dosing regimen or 2.0 mg 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 OPT-302 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 OPT-302 Phase 3 trials build upon and maintain key features for consistency with the Company's positive Phase 2b clinical trial of OPT-302, while evaluating the administration of OPT-302 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 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 OPT-302 every 4 weeks and every 8 weeks, followed by analysis in the predominantly classic lesions and total patient population.

The first patients were treated in our Phase 3 pivotal program in March 2021 in the US, and since that time, we have continued to activate clinical trial sites and recruit patients globally. In August 2021, the first sites commenced enrollment in Canada, followed subsequently with patients randomized in Europe, Asia Pacific and Latin America.

Opthea continues to expect to complete patient recruitment in the Phase 3 clinical trials of OPT-302 for the treatment of wet AMD by mid-2023, with topline data to be reported 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 OPT-302 for the treatment of wet AMD in the United States, European Union and other territories.

#### **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. If OPT-302 is approved in a major market, Carlyle and Abingworth will be eligible to receive fixed success payments 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 consists of two tranches. The first tranche for AU\$60.7 million (US\$41.9 million) was funded on August 24, 2022. Opthea will use reasonable best efforts to obtain shareholder approval to issue and consummate the second tranche, which will be for US\$47.5 million, or 59 million shares.

In February 2022, Opthea also announced the establishment of an "at the market" program whereby Opthea may offer and sell its ordinary shares in the form of American Depositary Shares, with an aggregate gross sales price of up to US\$75.0 million.

These financing arrangements strengthen Opthea's strategic position to maximize the value of OPT-302 and further validate our commitment to bring 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 expects to use the net proceeds from the non-dilutive financing and the private placement, together with its existing cash and cash equivalents, to continue advancing the clinical development of OPT-302 for the treatment of wet AMD, including the Phase 3 clinical trials, and anticipates that any remaining proceeds will fund pre-commercialization activities, including commercial scale manufacturing, team build and market shaping, as well as for working capital and general corporate purposes. Opthea believes its current cash and cash equivalents, together with the net proceeds from these transactions, will be sufficient to fund its operations and research and development expenses through at least the fourth calendar quarter of 2024.

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 timing of regulatory submissions, the performance and cost efficiency of third parties that assist Opthea with clinical development, including clinical research organizations ("CROs"), and the continuing impacts of the COVID-19 pandemic and macroeconomic challenges. Opthea has based its beliefs and expectations stated above on assumptions that may prove to be wrong, including due to the continued uncertainty relating to the COVID-19 pandemic and related macroeconomic challenges. Opthea may also experience future delays in its clinical development or commercialization of OPT-302 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 reach commercialization of OPT-302 in any indication, including 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.

Over the past 12 months, Opthea has worked to broaden Opthea's geographical reach by expanding its operations and building a US-based team of senior executives. In January 2022, Ms. Judith Robertson was appointed as the Company's first Chief Commercial Officer (CCO), after having formerly served as a non-executive member of the Opthea Board of Directors. This appointment was followed by the appointment of Dr. Joel Naor, MD, as Chief Medical Officer (CMO) in March 2022, and the subsequent appointment of several executives in Opthea's manufacturing, clinical operations and commercial divisions.

In addition, over the past 12 months, the Company further expanded its Board of Directors, which included welcoming Mr. Quinton Oswald and Dr. Susan Orr who have deep experience leading biotechnology companies and launching commercial products for the treatment of wet AMD and other ophthalmic diseases.

#### 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.

#### Impact of COVID-19

We are closely monitoring how the COVID-19 situation is affecting our employees, business, preclinical studies and clinical trials. In response to the COVID-19 pandemic, the Company followed the recommendations of the applicable State Government and when required, all of our employees transitioned to working remotely and travel was restricted. There is significant uncertainty relating to the trajectory of the pandemic, the impact of related responses and disruptions caused by the COVID-19 pandemic may result in difficulties or delays in initiating, enrolling, conducting or completing future clinical trials and the Company incurring unforeseen costs as a result of the disruptions in clinical supply or clinical trial delays.

The impact of COVID-19 on our future results will largely depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in Australia, the United States and other countries, business closures or business disruptions, the ultimate impact on financial markets and the global economy and the effectiveness of actions taken in Australia, the United States and other countries to contain and treat the disease. As previously disclosed, Opthea's efforts to advance its Phase 3 clinical trials, including clinical trial activations and trial site engagements, have been challenged in part by the COVID-19 pandemic and administrative delays. In particular, Opthea has incurred and experienced, and may continue to incur and experience in the future, significantly increased costs and delays in connection with the activities conducted by third-party CROs and other third parties to prepare for and progress Opthea's Phase 3 clinical trials.

#### **Future developments**

- Opthea's key objective over the next 12 months is to advance the ShORe and COAST Phase 3 clinical trials by continuing patient recruitment into the trials globally, with the objective of completing patient recruitment by mid-CY 2023.
- 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 to reach our objective of topline data readout mid-CY 2024.
- Over the following 12 months, we will also continue to raise the awareness of the commercial potential inherent in OPT-302 for the treatment of serious retinal diseases. Opthea will also continue to expand its management team and presence at international investment and clinical ophthalmology conferences and symposia, progress cGMP manufacturing activities of OPT-302 to support future commercial efforts and initiate pre-commercial activities to position OPT-302 as a promising therapeutic for the treatment of wet AMD.

#### Significant events after balance date

#### DEVELOPMENT AGREEMENT AND PIPE FUNDING

On August 12, 2022 (the "Effective Date"), Opthea Limited ("Opthea") entered into a Development Funding Agreement (the "Agreement") with Ocelot SPV LP ("Investor"), an affiliate of Carlyle and Abingworth, working together with Carlyle and Abingworth's recently formed development company Launch Therapeutics, pursuant to which 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 the Agreement, Investor has committed to provide Opthea US\$120 million in funding which may be increased up to US\$170 million at Investor's option, of which US\$50 million will be paid shortly after Opthea receives the proceeds from the first tranche of the PIPE (as defined below), with the remainder being funded in two additional tranches to be paid on December 31, 2022 and December 31, 2023, respectively. Pursuant to the Agreement, Opthea will be required to use commercially reasonable efforts to develop OPT-302 for the treatment of wet AMD in accordance with the Agreement, including pursuant to certain development timelines set forth therein.

In return, Opthea will pay to Investor (1) upon the first to occur of 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 payments payable over a six-year period thereafter, and (2) variable payments equal to 7% of net sales of OPT-302 for the treatment of wet AMD for each calendar quarter.

At the time that Investor receives an aggregate of four times the funding provided (US\$680 million if Investor funds the full US\$170 million under the Agreement) (the "Cap"), Opthea's payment obligations under the Agreement will be fully satisfied. Opthea has the option to satisfy its payment obligations to Investor upon Regulatory Approval or a change of control of Opthea by paying an amount equal to the present value of the remaining payments payable to Investor subject to a mid-single-digit discount rate. Opthea also has an option to buy out the remaining payments at any time by paying an amount equal to the remaining payments due subject to a proposed discount rate, which Investor may accept or reject. Upon a change of control of Opthea, an acceleration payment of a specified multiple of the funding provided is payable, net of payments already made to Investor and creditable against future payments to Investor.

Opthea will grant Investor a security interest in all of its assets (other than intellectual property not related to OPT-302). The security interest will terminate when Investor receives payments and/or change of control acceleration payments equal to two times the funding provided or upon certain terminations of the Agreement (the "Release Date"). The Agreement also includes customary representations and warranties and covenants, including certain negative covenants regarding limitations on incurrence of indebtedness, liens, investments, restricted payments, sales of assets, and royalty sales. The negative covenants will terminate upon the Release Date.

The Agreement terminates upon the payment of all payments owing to Investor, unless earlier terminated by Investor if:

- Opthea fails to comply with certain covenants and agreements set forth in the Agreement, including failure to make required payments or develop OPT-302 as set forth in the Agreement;
- Opthea suffers a material adverse event;
- there is a material adverse patent impact on Opthea's intellectual property covering OPT-302;
- there are certain irresolvable disagreements within the joint steering committee overseeing Opthea's development of OPT-302;
- the security interests of Opthea are invalidated or terminated other than as set forth in the Agreement; or
- any Phase 3 clinical trial of OPT-302 is completed or terminated and (1) the primary endpoint is not met or (2) Investor reasonably determines that the results of any such trial do not support regulatory approval.

The Agreement may also be earlier terminated by Opthea if Investor fails to fund as provided in the Agreement. The Agreement may be terminated by either party (i) if the other party materially breaches the Agreement ("Material Breach"), (ii) if OPT-302 fails to receive regulatory approval in the United States or European Union, (iii) upon the bankruptcy of the other party, (iv) if a serious safety concern arises in an OPT-302 clinical trial or (v) upon a change of control of Opthea.

In certain instances, upon the termination of the Agreement, Opthea will be obligated to pay Investor a multiple of the amounts paid to Opthea under the Agreement, including specifically,

- up to the Cap in the event that Investor terminates the agreement due to (w) failure by Opthea to comply with certain covenants and agreements set forth in the Agreement, including failure to make required payments or develop OPT-302 as set forth in the Agreement, (x) the bankruptcy of Opthea, (y) a safety concern resulting from gross negligence on the part of Opthea or due to a safety concern that was material on the Effective Date and the material data showing such safety concern was not publicly known, disclosed to Investor, or in the diligence room made available to Investor or (z) the security interests of Investor being invalidated or terminated other than as set forth in the Agreement;
- several multiples of such amounts in the event the Agreement is terminated due to Material Breach by Opthea; and
- a small multiple of such amounts in the event of certain irresolvable disagreements within the executive review committee overseeing Opthea's development of OPT-302.

In addition, if following certain events of termination of the Agreement, Opthea continues to develop OPT-302 for the treatment of wet AMD and obtains Regulatory Approval, it will make the payments to Investor as if the Agreement had not been terminated, less any payments made upon termination.

The Agreement also provides that Opthea will use reasonable best efforts to complete a private placement of its ordinary shares or American Depositary Shares ("ADS's") representing its ordinary shares (at a ratio of 8 ordinary shares per ADS) for gross proceeds of at least US\$70 million, which Opthea expects will be satisfied through the PIPE (as described below).

The Agreement also includes a minimum cash requirement, and Opthea may need to obtain additional funding to meet this requirement in the future, including prior to the expected readout of top-line results for its Phase 3 clinical trials. To the extent that Opthea raises additional capital through the sale of equity or convertible debt securities to meet this requirement, Opthea's equity holders will be diluted.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by the full text of the Agreement, a copy of which will be filed as an exhibit to Opthea's Annual Report on Form 20-F for the fiscal year ended June 30, 2022, which will be subsequently filed with the Securities and Exchange Commission.

Concurrently with the execution of the Agreement, Opthea entered into binding commitments for the private placement of ordinary shares to be issued pursuant to Regulation S under, and Section 4(a)(2) of, the Securities Act of 1933, as amended (the "Securities Act"), as the case may be, for aggregate gross proceeds of approximately US\$90 million (the "PIPE") and a price per ordinary share of AU\$1.15 (approximately US\$0.81).

The PIPE consists of two tranches. The first tranche will be for AU\$60.7 million (US\$41.9 million), or 52.8 million ordinary shares, which amount represents the amount of new ordinary shares that Opthea may currently issue without obtaining shareholder approval under ASX Listing Rules. The first tranche was received on August 24, 2022. Opthea will use reasonable best efforts to obtain shareholder approval to issue and consummate the second tranche, which will be for US\$47.5 million, or 59 million shares.

Opthea expects to issue a Notice of Meeting to its shareholders to convene a general meeting of shareholders expected in September 2022 to obtain shareholder approval to issue and consummate the second tranche.

#### APPROVAL OF ADVANCED OVERSEAS FINDING CERTIFICATE

On August 29, 2022, the Company obtained an Advanced Overseas Finding Certificate from AusIndustry for additional overseas research activities for OPT-302. This is a non-adjusting subsequent event.

Besides the above-mentioned subsequent events, there are no other significant events after June 30, 2022, to report.

#### **Environmental regulations**

The Company is not subject to significant environmental regulations.

#### Indemnification and insurance

During the financial year ended June 30, 2021, the Company indemnified its directors, the company secretary and executive officers in respect of any acts or omissions giving rise to a liability to another person (other than the Company or a related party) unless the liability arose out of conduct involving a lack of good faith. In addition, the Company indemnified the directors, the company secretary and executive officers against any liability incurred by them in their capacity as directors, company secretary or executive officers in successfully defending civil or criminal proceedings in relation to the Company. No monetary restriction was placed on this indemnity.

The Company has insured its directors, the company secretary and executive officers for the financial year ended June 30, 2022. Under the Company's Directors' and Officers' Liabilities Insurance Policy, the Company shall not release to any third party or otherwise publish details of the nature of the liabilities insured by the policy or the amount of the premium. Accordingly, the Company relies on section 300(9) of the *Corporations Act 2001* to exempt it from the requirement to disclose the nature of the liability insured against and the premium amount of the relevant policy.

#### Directors' meetings

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

#### Meetings of committees

Directors' meetings	Audit & risk	Nomination	Remuneration
7	7	2	5
7	6		3
7	7	2	5
7	6	2	5
7	7	2	3
7	4		5
4	5		3
1	1		_
1	1		
7	7		3
	7 7 7 7 7 7 7 7	meetings         Audit & risk           7         7           7         6           7         7           6         7           7         6           7         7           7         4	meetings         Audit & risk         Nomination           7         7         2           7         6         2           7         6         2           7         6         2           7         7         2           7         7         2           7         4         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	Remuneration
Daniel Spiegelman (Chairman)	Lawrence Gozlan (Chairman)	Michael Sistenich (Chairman)
Michael Sistenich	Michael Sistenich	Lawrence Gozlan
Lawrence Gozlan (appointed February 24, 2022)	Daniel Spiegelman	Julia Haller
Judith Robertson (resigned January 1, 2022)	-	

#### 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 85 and forms part of the directors' report for the financial year ended June 30, 2022.

#### 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, 2022. The term 'key management personnel' refers to those persons having authority and responsibility for planning, directing and controlling the activities of the Group, directly or indirectly, including any director (whether executive or otherwise) of the Group.

#### KEY MANAGEMENT PERSONNEL

The directors and other key management personnel of the Group during or since the end of the financial year were:

#### Non-executive directors

Jeremy Levin (appointed October 5, 2020)	Chairman, Non-executive director
Julia Haller	Non-executive director
Daniel Spiegelman	Non-executive director
Michael Sistenich	Non-executive director
Lawrence Gozlan	Non-executive director
Susan Orr (appointed April 21, 2022)	Non-executive director
Quinton Oswald (appointed April 21, 2022)	Non-executive director
Judith Robertson (resigned January 1, 2022)	Non-executive director

#### **Executive officers**

Megan Baldwin	Chief Executive Officer and Managing Director
Karen Adams	Vice President Finance and Company Secretary
Judith Robertson (appointed January 1, 2022)	Chief Commercial Officer
Joel Naor (appointed March 1, 2022)	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.

#### PRINCIPLES OF COMPENSATION

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

#### DIVERSITY

The directors consider annually if the diversity of the Company's personnel is appropriate. During the three years ended June 30, 2022, 37.9% of the directors and 53.9% of employees were female.

#### FIXED COMPENSATION

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

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

Fixed compensation comprises salary and superannuation and is reviewed every 12 months by the remuneration committee. No external advice has been sought during either 2022 or 2021.

#### PERFORMANCE LINKED COMPENSATION

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

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

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

The remuneration committee considered the STI payment for the 2022 financial year in August 2022. Based on the achievement of operational objectives in the financial year, the remuneration committee has determined there will be US\$261,456 STI bonus paid to KMP for the 2022 financial year (2021: US\$244,145).

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

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

#### CONSEQUENCES OF PERFORMANCE ON SHAREHOLDER WEALTH

In considering the Company's performance and benefits for shareholder wealth, the remuneration committee have regard to operational contributions and the following indices in respect of the current and previous four financial years. 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 AU\$. Refer to Note 3 Change in presentation and functional currencies for more information in regard to the determination of the change.

	2022 US\$	2021 US\$	2020 A\$	2019 A\$	2018 A\$
Revenue including finance income	326,151	440,615	539,514	914,840	1,143,822
Loss before tax	(99,116,657)	(50,283,342)	(16,831,966)	(35,547,034)	(28,919,488)
Tax benefit	6,299,286	4,938,846	5,708,767	14,636,973	12,017,248
Loss after tax	(92,817,371)	(45,344,496)	(11,123,199)	(20,910,061)	(16,902,240)

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

	2022 US\$	2021 US\$	2020 A\$	2019 A\$	2018 A\$
Basic loss per share	(0.26)	(0.14)	(0.04)	(0.09)	(0.04)
Net Tangible Asset (NTA) backing per share @ June 30	0.20	0.58	0.17	0.12	0.19
Opthea share price @ June 30	A\$1.10	A\$1.34	A\$2.36	A\$0.67	A\$0.53

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) Megan:

- Receives fixed remuneration of AU\$470,422 per annum from July 1, 2021.
- 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 Megan's remuneration plus implied bonus.

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

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

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

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 cover 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.

Joel Naor, Chief Medical 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 cover costs.

The Company may terminate Joel Naor'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 AU\$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 and Remuneration US\$10,000/AU\$13,140, and general committee fees of US\$5,000/AU\$6,570 per annum.

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

The Company implemented a non-executive director share and option plan (NED Plan) following its approval at the 2014 AGM. Approval of further grant of options to non-executive directors under the NED Plan was made at the 2018 AGM. Under the NED Plan, present and future non-executive directors may:

- Elect to receive newly issued ordinary shares (Shares) or options to acquire newly issued Shares in lieu of receiving some or all of their entitlement to their director's existing cash remuneration (in accordance with article 61.8 of the Company's constitution);
- Be awarded newly issued Shares or options to acquire newly issued Shares in lieu of additional cash remuneration in respect of services provided to the Company which in the opinion of the Board are outside the scope of the ordinary duties of the relevant director (in accordance with article 61.5 of the Company's constitution); and/or
- Otherwise be awarded newly issued Shares or options to acquire newly issued Shares as part of the directors' remuneration in addition to any existing cash remuneration paid to directors (if any).

Advantages of the NED Plan are that it:

- Assists the Company in preserving its cash for use towards advancing the Company's lead molecule, OPT-302, through Phase 2 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- Employ- ment	Long Term	Termin- ation benefits	Shared based payment		Total
		Salary & Fees US\$	Cash bonus <sup>1</sup> US\$	Super- annu- ation US\$	Long Service Leave US\$	Termin- ation Pay US\$	Options US\$	Total US\$	perfor- mance related %
Non-Executive direc	ctors:								
Jeremy Levin	2022	75,000		-		-	858,286	933,286	92%
	2021	54,032	-	-	-	-	1,158,465	1,212,497	96%
Geoffrey Kempler <sup>2</sup>	2022	-	_	-	-	-	-		0%
	2021	21,534	-	2,046	-	=	=	23,580	0%
Michael Sistenich	2022	73,789	-	-	-	-	-	73,789	0%
	2021	64,344	-	-	-	-	_	64,344	0%
Lawrence Gozlan <sup>3</sup>	2022	70,201	-	-	-	-	586,271	656,472	89%
	2021	60,416	-	_	-	=	1,252,173	1,312,589	95%
Daniel Spiegelman <sup>4</sup>	2022	75,000	_	-	-	-	696,217	771,217	90%
	2021	64,583	_	_	_	-	1,487,000	1,551,583	96%
Julia Haller <sup>5</sup>	2022	55,000	_	-	-	-	587,694	642,694	91%
	2021	4,250	_	_	_	-	_	4,250	0%
Susan Orr <sup>6</sup>	2022	9,583	_	-	-	-	128,010	137,593	93%
	2021	_	_		_	-	_		0%
Quinton Oswald <sup>7</sup>	2022	9,583	-	-	-	-	128,010	137,593	93%
	2021	_	_	_	_	-	_	_	0%
Judith Robertson <sup>8</sup>	2022	27,500	-	-	-	-	358,633	386,133	93%
	2021	4,250	-	_	-	=	-	4,250	0%
Sub-total									
Non-executive	2022	395,656	-		-	-	3,343,121	3,738,777	89%
directors	2021	273,409	_	2,046	_	_	3,897,638	4,173,093	93%

			Short Term		Long Term	-	Shared based payment		<b>T</b>
		Salary & Fees US\$	Cash bonus¹ US\$	Super- annu- ation US\$	Long Service Leave US\$	Termin- ation Pay US\$	Options US\$	Total US\$	Total perfor- mance related %
Executive directors:									
Megan Baldwin	2022	342,510	113,475	34,251	-	-	730,644	1,220,880	76%
	2021	338,618	147,166	45,666	-	_	_	531,450	28%
Other Key Manager	nent Pers	sonnel:							
Karen Adams <sup>9</sup>	2022	211,035	27,981	21,104	-	-	119,147	379,267	39%
	2021	31,039	_	2,949	_	-	_	33,988	0%
Judith Robertson <sup>8</sup>	2022	195,000	78,000	-	-	-	229,060	502,060	61%
	2021	-	_	-	-	-	-	_	-%
Joel Naor <sup>10</sup>	2022	150,000	42,000	750	-	-	242,795	435,545	65%
	2021	_	_	-	-	-	-	_	-%
Mike Tonroe <sup>11</sup>	2022	-	-	_	-	-	-	-	-%
	2021	237,535	71,314	28,889	_	-	_	337,738	21%
Totals	2022	1,294,201	261,456	56,105	_	-	4,664,767	6,276,529	80%
	2021	880,601	218,480	79,550	-	-	3,897,638	5,076,269	81%

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

<sup>2.</sup> Director resigned October 12, 2020.

<sup>3.</sup> Lawrence Gozlan was appointed as a non-executive director on July 24, 2020. Mr. Gozlan's annual director fee is AU\$65,700.

<sup>4.</sup> Director appointed September 10, 2020.

<sup>5.</sup> Director appointed June 1, 2021.

<sup>6.</sup> Director appointed April 21, 2022.

<sup>7.</sup> Director appointed April 21, 2022.

<sup>8.</sup> Director resigned January 1, 2022, appointed CCO January 1, 2022.

<sup>9.</sup> Appointed June 15, 2021.

<sup>10.</sup> Appointed CMO March 1, 2022.

<sup>11.</sup> Resigned June 24, 2021.

#### **EQUITY INSTRUMENTS**

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

#### OPTIONS OVER EQUITY INSTRUMENTS GRANTED AS COMPENSATION

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

	During the fin	ancial year
Name	Number of options granted	Number of options vested <sup>12</sup>
Julia Haller	2,000,000	500,000
Judith Robertson	2,000,000	500,000
Susan Orr	1,000,000	250,000
Quinton Oswald	1,000,000	250,000
Karen Adams	800,000	200,000

Options Granted during the year have the following Fair values at Grant date, US\$0.705 (AU\$0.526), US\$0.535 (AU\$0.397) and US\$0.675 (AU\$0.937) with the following exercise price US\$0.948 (AU\$1.27), US\$0.755 (AU\$1.01) and US\$1.46 (AU\$2.03), for Julia and Judith, Susan and Quinton and Karen 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:

	During the final	During the financial year		
Name	Number of options granted	Number of options vested		
	1,600,000	69,589		

Performance rights granted during the year have the following Fair value at Grant date US\$0.955 (AU\$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.

<sup>12.</sup> Options that are vested during the financial year were originally granted in the year ended June 30, 2022.

## 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:

During the final	During the financial year		
Number of options granted	Number of options vested		
300,000	-		

American depository securities options granted during the year have the following fair value at grant date US\$4.116 with an exercise price of 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 2021, 5,845,804 shares were issued to KMP on the exercise of 8,400,000 of options previously granted as compensation.

During 2021, 8,400,000 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 5,845,804 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 AU\$1.672 for 7,000,000 options and AU\$1.647 for 1,400,000 options and an exercise price of AU\$0.48 for 7,800,000 options and AU\$0.855 for 600,000 options.

Name	No. of options exercised	No. of ordinary shares of Opthea Limited issued	Issue date	Amount unpaid	Expiry date of Rights
Megan Baldwin	4,000,000	2,851,675	March 7, 2016	\$nil	March 7, 2021
Geoffrey Kempler	2,000,000	1,425,837	March 7, 2016	\$nil	March 7, 2021
Michael Sistenich	1,000,000	712,919	March 7, 2016	\$nil	March 7, 2021
Mike Tonroe	800,000	566,849	March 31, 2016	\$nil	January 1, 2022
Mike Tonroe	600,000	288,524	April 3, 2019	\$nil	April 3, 2023
	8,400,000	5,845,804			

#### 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>13</sup>	Financial years in which grant vests	Vesting conditions
Megan Baldwin	1,320,000	March 7, 2016	100%	0%	July 1, 2015	Continued service
-	1,320,000	March 7, 2016	100%	0%	July 1, 2016	
-	1,360,000	March 7, 2016	100%	0%	July 1, 2017	
-	3,000,000	November 29, 2018	100%	0%	July 1, 2019	
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	
Geoffrey Kempler	660,000	March 7, 2016	100%	0%	July 1, 2015	Continued service
	660,000	March 7, 2016	100%	0%	July 1, 2016	
-	680,000	March 7, 2016	100%	0%	July 1, 2017	
	1,500,000	November 29, 2018	100%	0%	July 1, 2019	
Michael Sistenich	330,000	March 7, 2016	100%	0%	July 1, 2015	Continued service
-	330,000	March 7, 2016	100%	0%	July 1, 2016	
-	340,000	March 7, 2016	100%	0%	July 1, 2017	
-	1,500,000	November 29, 2018	100%	0%	July 1, 2019	
Daniel Spiegelman	500,000	October 12, 2020	100%	0%	July 1, 2020	Continued service
-	500,000	October 12, 2020	0%	0%	July 1, 2021	
-	500,000	October 12, 2020	0%	0%	July 1, 2022	
-	500,000	October 12, 2020	0%	0%	July 1, 2023	
Lawrence Gozlan	500,000	October 12, 2020	100%	0%	July 1, 2020	Continued service
-	500,000	October 12, 2020	0%	0%	July 1, 2021	
-	500,000	October 12, 2020	0%	0%	July 1, 2022	
-	500,000	October 12, 2020	0%	0%	July 1, 2023	
Julia Haller	500,000	October 19, 2021	100%	0%	July 1, 2021	Continued service
-	500,000	October 19, 2021	0%	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	0%	0%	July 1, 2023	
-	250,000	April 24, 2022	0%	0%	July 1, 2024	
-	250,000	April 24, 2022	0%	0%	July 1, 2025	
		-				

<sup>13.</sup> The percentage forfeited in the year represents the reduction from the maximum number of options available to vest due to vesting criteria not being achieved.

	Number of options	Grant date	% Vested	% Forfeited <sup>13</sup>	Financial years in which grant vests	Vesting conditions
Quinton Oswald	250,000	April 24, 2022	100%	0%	July 1, 2022	Continued service
	250,000	April 24, 2022	0%	0%	July 1, 2023	
	250,000	April 24, 2022	0%	0%	July 1, 2024	
	250,000	April 24, 2022	0%	0%	July 1, 2025	
Karen Adams	200,000	June 6, 2022	100%	0%	July 1, 2022	Continued service
	200,000	June 6, 2022	0%	0%	July 1, 2023	
	200,000	June 6, 2022	0%	0%	July 1, 2024	
	200,000	June 6, 2022	0%	0%	July 1, 2024	

#### 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>14</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	0%	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

#### 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>15</sup>	Financial years in which grant vests	Vesting conditions
Joel Naor	75,000	March 1, 2023	0%	0%	July 1, 2022	Continued service
	6,250 monthly for 36 months	April 1, 2023 – Mar 1, 2026	0%	0%	July 1, 2023 - 2026	

<sup>14.</sup> The percentage forfeited in the year represents the reduction from the maximum number of options available to vest due to vesting criteria not being achieved.

<sup>15.</sup> The percentage forfeited in the year represents the reduction from the maximum number of options available to vest due to vesting criteria not being achieved.

#### **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 compen- sation	Options exercised	Lapsed	Forfeited	Held at June 30	Vested during the year	Vested and exercisable
Megan Baldwin	2022	3,000,000	-	-	-	-	3,000,000	-	3,000,000
	2021	7,000,000	-	(4,000,000)			3,000,000	-	3,000,000
Jeremy Levin	2022	3,000,000	-	=	_	-	3,000,000	750,000	1,500,000
	2021	=	3,000,000	=	=	=	3,000,000	750,000	750,000
Geoffrey Kempler <sup>16</sup>	2022	1,500,000	-	=	=	-	1,500,000	=	1,500,000
	2021	3,500,000	-	(2,000,000)	=	=	1,500,000	=	1,500,000
Daniel Spiegelman	2022	2,000,000	-	=	=	-	2,000,000	500,000	1,000,000
	2021	=	2,000,000	=	=	=	2,000,000	500,000	500,000
Lawrence Gozlan	2022	2,000,000	-	-	_	-	2,000,000	500,000	1,000,000
	2021	_	2,000,000	=	=	-	2,000,000	500,000	500,000
Michael Sistenich	2022	1,500,000	-	=	=	-	1,500,000	=	1,500,000
	2021	2,500,000	=	(1,000,000)	=	=	1,500,000	=	1,500,000
Julia Haller	2022		2,000,000	-	-	-	2,000,000	500,000	500,000
	2021	_	=	=	=	=	=	=	=
Susan Orr	2022	-	1,000,000	-	-	-	1,000,000	250,000	250,000
	2021		=	=	=	=	=	-	=
Quinton Oswald	2022	-	1,000,000	-	-	-	1,000,000	250,000	250,000
	2021	_	-	=	=	-	=	-	_
Other executives:									
Mike Tonroe <sup>17</sup>	2022	-	-	-	-	-	-	-	-
	2021	1,400,000	-	(1,400,000)	-	-	0	0	0
Karen Adams	2022	-	800,000	-	-	-	800,000	200,000	200,000
	2021		_	_	_	_	_	_	_
Judith Robertson	2022	-	2,000,000	-	-	-	2,000,000	500,000	500,000
	2021	_	-	-	_	-	-	_	-
Total	2022	13,000,000	6,800,000	-	-	-	19,800,000	3,450,000	11,200,000
	2021	14,400,000	7,000,000	(8,400,000)	_	-	13,000,000	1,750,000	7,750,000

<sup>16.</sup> Geoffrey Kempler resigned October 12, 2020.

<sup>17.</sup> Mike Tonroe resigned at June 24, 2021. All options had been converted prior to his resignation.

Number of performance rights		Held at July 1	Granted as compen- sation	Rights exercised	Lapsed	Forfeited	Held at June 30	Vested during the year	Vested and exercisable
Megan Baldwin	2022	-	1,600,000	-	-	-	1,600,000	69,589	69,589
	2021	-	=	=	-	=	=	=	=
Total	2022	-		=	-	-	1,600,000	69,589	69,589
	2021	-	-	-	-	-	-	_	-
Number of ADS options		Held at July 1	Granted as compen- sation	ADS options exercised	Lapsed	Forfeited	Held at June 30	Vested during the year	Vested and exercisable
	2022		compen-	options	Lapsed -	Forfeited -		during	
ADS options	2022		compen- sation	options	Lapsed - -	Forfeited -	June 30	during	
ADS options			compen- sation	options	Lapsed	Forfeited	June 30	during	

#### 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
Non-executive direct	ors						
Jeremy Levin	2022	_	_	_	_	-	-
	2021	_	_	_	_	_	_
Geoffrey Kempler <sup>18</sup>	2022	2,326,797	-	-	-	-	2,326,797
	2021	900,960	_	1,425,837	_	_	2,326,797
Michael Sistenich	2022	1,233,097	-	-	-	-	1,233,097
	2021	520,178	-	712,919	-	-	1,233,097
Daniel Spiegelman	2022	-	-	-	-	-	-
	2021	-	-	_	-	-	-
Lawrence Gozlan	2022	1,877,357	_	_	-	-	1,877,357
	2021	-	-	_	1,877,357	-	1,877,357
Julia Haller	2022	_			_	_	_
	2021	-	-	_	_	-	_
Susan Orr	2022	-	_	-	-	-	_
	2021	-	-	_	_	-	_
Quinton Oswald	2022	-	_	-	-	-	-
	2021	_	-	_	_	-	_
Judith Robertson (resigned	2022	-	-	-	-	-	-
January 1, 2022)	2021	=	=	_	-	=	_
Executives							
Megan Baldwin	2022	3,839,398	-	-	-	=	3,839,398
	2021	987,723	-	2,851,675	-	-	3,839,398
Karen Adams	2022	-	-	_	-	_	_
	2021	-	-	_	_	-	_
Judith Robertson	2022	-	_	_	-	-	-
	2021	-	-	_	_	_	_
Joel Naor	2022	_	_	=	-	=	-
	2021	_	_	_	_	_	_
Mike Tonroe <sup>19</sup>	2022	_	-	_	-	-	-
	2021	_	_	855,373	-	(855,373)	-
Total	2022	9,276,649	_	-	_	-	9,276,649
	2021	2,408,861	-	5,845,804	1,877,357	(855,373)	9,276,649

<sup>18.</sup> Geoffrey Kempler resigned as at October 12, 2020.

<sup>19.</sup> Mike Tonroe resigned as at June 24, 2021.

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 August 30, 2022.

For and on behalf of the board:

Megan Baldwin

CEO & Managing Director

Opthea Limited

Melbourne

August 30, 2022

### 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.



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.



**Joel Naor** *MD, MBA, MSc*Chief Medical
Officer

Dr. Joel Naor was appointed Chief Medical Officer of Opthea in March 2022.

Dr. Joel Naor has over two decades of experience leading clinical development programs that target retina conditions encompassing biologics, small molecules, sustained release technologies, stem cells and photodynamic therapy. In his most recent role, he served as Vice President of Clinical Science and Development Operations at Kodiak Sciences Inc. Previously, Dr. Naor was the Chief Medical Officer for Macusight, Inc. until the company was acquired by Santen Inc. in 2010, and subsequently served as Vice President and Head of Global Medical Affairs for Santen Inc. He has also held leadership positions at Allergan Inc., QLT Inc. and Stem Cells Inc. Dr. Joel Naor received his Doctor of Medicine (M.D.) from the Technion - Israel Institute of Technology and completed training in Ophthalmology at the University of Toronto. He holds a Master of Science (MSc.) in Epidemiology from the University of Toronto and a Master of Business Administration (M.B.A.) from Simon Fraser University in Vancouver.

### Management Team (cont.)



**Judith Robertson**Chief Commercial
Officer

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

Ms. Robertson was most recently Chief Commercial Officer of Fleusis 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.



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.



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.

### Management Team (cont.)



**lan 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.



**Clare Price BPHARM**Director of Clinical Development

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

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

For the remaining three years Clare formed part of the project management group of the newly merged GlaxoSmithKline, responsible for the project management of full drug development programs from molecule inception through non-clinical and clinical studies, regulatory aspects and commercialization.

Clare has held senior clinical roles in two ASX-listed biotechnology companies, firstly Acrux, and then Starpharma. Over her nine years at Starpharma she implemented and delivered successful Phase 2 and 3 clinical programs, including extensive regulatory interaction and negotiation, leading to the successful commercialization of the lead candidate product.

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



**Annette Leahy**Director –
Clinical Research

Annette Leahy commenced at Opthea in August 2017 as Director of Clinical Research. Annette has 20 years clinical research experience including operational and project management roles across biotechnology, pharmaceutical, and CRO industries.

Prior to joining Opthea Annette held senior operational roles at Swisse and Novotech successfully building clinical trial teams and departments.

Annette also has 12 years project management experience including leading a global influenza clinical trials program under a US government contract at Biota, managing early phase clinical studies in a Phase 1 unit at Nucleus Network and managing European clinical projects while living in the UK and working for Mitsubishi Tanabe Pharma Europe.

Annette has a Bachelor of Health Information Management from La Trobe University.

# Financial Report

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# Consolidated Statement of Profit or Loss and Other Comprehensive Income

#### For the year ended June 30, 2022

Other income       8       108,322       26,950         Research and development expenses       9       (78,654,217)       (25,891,851,851,851,851,851,851,851,851,851,85		Note	2022 US\$	2021 US\$
Research and development expenses       9 (78,654,217)       (25,891,851,851,851,851,851,851,851,851,851,85	Revenue	7	90,683	68,613
Patent expenses       (131,788)       (137,666)         Intellectual property costs       (28,713)       (291,235)         Administrative expenses       10       (17,901,112)       (13,399,748)         Occupancy expenses       (21,307)       (18,445)         Finance income – interest income       11       235,468       372,001         Net foreign exchange loss       12       (2,813,993)       (11,011,961)         Loss before income tax       (99,116,657)       (50,283,342)         Income tax benefit       13       6,299,286       4,938,846         Loss for the year       (92,817,371)       (45,344,496)         Other comprehensive income       Items that will not be reclassified subsequently to profit or loss:       -       469,767         Other comprehensive income for the year, net of tax       -       469,767       469,767         Other comprehensive income for the year, net of tax       -       469,767       469,767       448,747,299         Loss for the year is attributable to:       (92,817,371)       (44,874,729)       448,744,729         Cowners of the Company       (92,817,371)       (45,344,496)       469,767       469,767       469,767       469,767       469,767       469,767       469,767       469,767       469,767	Other income	8	108,322	26,950
Intellectual property costs  Administrative expenses  Administrative expenses  10 (17,901,112) (13,399,748, 10,212) (13,399,748, 10,212) (13,399,748, 10,212) (13,399,748, 10,212) (13,399,748, 10,212) (13,399,748, 10,212) (13,399,748, 10,212) (13,399,748, 10,212) (13,399,748, 10,212) (13,399,748, 10,212) (14,814,96) (	Research and development expenses	9	(78,654,217)	(25,891,851)
Administrative expenses Occupancy expenses (21,307) (18,445 Finance income – interest income 11 235,468 372,001 Net foreign exchange loss 12 (2,813,993) (11,011,961) Loss before income tax (99,116,657) (50,283,342) Income tax benefit 13 6,299,286 4,938,846 Loss for the year (92,817,371) (45,344,496) Other comprehensive income Items that will not be reclassified subsequently to profit or loss: Fair value gains on investments in financial assets - 469,767 Other comprehensive income for the year, net of tax - 469,767 Total comprehensive loss for the year (92,817,371) (44,874,729) Loss for the Company 23 (92,817,371) (45,344,496) Total comprehensive loss for the year is attributable to: Owners of the Company (92,817,371) (44,874,729) Total comprehensive loss for the year is attributable to: Owners of the Company (92,817,371) (44,874,729) (92,817,371) (44,874,729) (92,817,371) (44,874,729) (92,817,371) (44,874,729) (92,817,371) (44,874,729) (92,817,371) (44,874,729)	Patent expenses		(131,788)	(137,666)
Occupancy expenses         (21,307)         (18,445)           Finance income – interest income         11         235,468         372,001           Net foreign exchange loss         12         (2,813,993)         (11,011,961)           Loss before income tax         (99,116,657)         (50,283,342)           Income tax benefit         13         6,299,286         4,938,846           Loss for the year         (92,817,371)         (45,344,496)           Other comprehensive income         Items that will not be reclassified subsequently to profit or loss:         -         469,767           Other comprehensive income for the year, net of tax         -         469,767           Total comprehensive loss for the year         (92,817,371)         (44,874,729)           Loss for the year is attributable to:         (92,817,371)         (45,344,496)           Owners of the Company         23         (92,817,371)         (45,344,496)           Total comprehensive loss for the year is attributable to:         (92,817,371)         (44,874,729)           Cowners of the Company         (92,817,371)         (44,874,729)           Loss per share attributable to the owners of the Company:         (92,817,371)         (44,874,729)	Intellectual property costs		(28,713)	(291,235)
Finance income – interest income  Net foreign exchange loss  12 (2,813,993) (11,011,961)  Loss before income tax (99,116,657) (50,283,342) Income tax benefit 13 6,299,286 4,938,846  Loss for the year (92,817,371) (45,344,496)  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  Cother comprehensive loss for the year (92,817,371) (44,874,729)  Loss for the year is attributable to:  Owners of the Company 23 (92,817,371) (45,344,496)  Total comprehensive loss for the year is attributable to:  Owners of the Company (92,817,371) (44,874,729)  (92,817,371) (44,874,729)  (92,817,371) (44,874,729)  (92,817,371) (44,874,729)  (92,817,371) (44,874,729)  (92,817,371) (44,874,729)	Administrative expenses	10	(17,901,112)	(13,399,748)
Net foreign exchange loss       12       (2,813,993)       (11,011,961)         Loss before income tax       (99,116,657)       (50,283,342)         Income tax benefit       13       6,299,286       4,938,846         Loss for the year       (92,817,371)       (45,344,496)         Other comprehensive income letems that will not be reclassified subsequently to profit or loss:       469,767         Fair value gains on investments in financial assets       -       469,767         Other comprehensive income for the year, net of tax       -       469,767         Total comprehensive loss for the year       (92,817,371)       (44,874,729)         Loss for the year is attributable to:       (92,817,371)       (45,344,496)         Total comprehensive loss for the year is attributable to:       (92,817,371)       (44,874,729)         Owners of the Company       (92,817,371)       (44,874,729)         Cowners of the Company       (92,817,371)       (44,874,729)         Loss per share attributable to the owners of the Company:       (92,817,371)       (44,874,729)	Occupancy expenses		(21,307)	(18,445)
Loss before income tax  Income tax benefit  In	Finance income – interest income	11	235,468	372,001
Income tax benefit 13 6,299,286 4,938,846  Loss for the year (92,817,371) (45,344,496)  Other comprehensive income  Items that will not be reclassified subsequently to profit or loss:  Fair value gains on investments in financial assets - 469,767  Other comprehensive income for the year, net of tax - 469,767  Total comprehensive loss for the year (92,817,371) (44,874,729)  Loss for the year is attributable to:  Owners of the Company 23 (92,817,371) (45,344,496)  Total comprehensive loss for the year is attributable to:  Owners of the Company (92,817,371) (44,874,729)  Comprehensive loss for the year is attributable to:  Owners of the Company (92,817,371) (44,874,729)  Loss per share attributable to the owners of the Company:	Net foreign exchange loss	12	(2,813,993)	(11,011,961)
Income tax benefit 13 6,299,286 4,938,846  Loss for the year (92,817,371) (45,344,496)  Other comprehensive income  Items that will not be reclassified subsequently to profit or loss:  Fair value gains on investments in financial assets - 469,767  Other comprehensive income for the year, net of tax - 469,767  Total comprehensive loss for the year (92,817,371) (44,874,729)  Loss for the year is attributable to:  Owners of the Company 23 (92,817,371) (45,344,496)  Total comprehensive loss for the year is attributable to:  Owners of the Company (92,817,371) (44,874,729)  Comprehensive loss for the year is attributable to:  Owners of the Company (92,817,371) (44,874,729)  Loss per share attributable to the owners of the Company:				
Cother 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  Total comprehensive loss for the year  Loss for the year is attributable to: Owners of the Company  Total comprehensive loss for the year is attributable to: Owners of the Company  Total comprehensive loss for the year is attributable to: Owners of the Company  (92,817,371)  (44,874,729)  (92,817,371)  (44,874,729)  (92,817,371)  (44,874,729)  (92,817,371)  (44,874,729)  (92,817,371)  (44,874,729)  (92,817,371)	Loss before income tax		(99,116,657)	(50,283,342)
Other comprehensive income Items that will not be reclassified subsequently to profit or loss: Fair value gains on investments in financial assets  - 469,767  Other comprehensive income for the year, net of tax  - 469,767  Total comprehensive loss for the year  (92,817,371)  (44,874,729)  Cowners of the Company  23 (92,817,371)  (45,344,496)  (92,817,371)  (45,344,496)  (92,817,371)  (44,874,729)  (92,817,371)  (44,874,729)  (92,817,371)  (44,874,729)  (92,817,371)  (44,874,729)  (92,817,371)  (44,874,729)	Income tax benefit	13	6,299,286	4,938,846
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  - 469,767  Total comprehensive loss for the year  (92,817,371) (44,874,729)  Loss for the year is attributable to:  Owners of the Company  Total comprehensive loss for the year is attributable to:  Owners of the Company  (92,817,371) (45,344,496)  (92,817,371) (44,874,729)  (92,817,371) (44,874,729)  (92,817,371) (44,874,729)  Loss per share attributable to the owners of the Company:	Loss for the year		(92,817,371)	(45,344,496)
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  - 469,767  Total comprehensive loss for the year  (92,817,371) (44,874,729)  Loss for the year is attributable to:  Owners of the Company  Total comprehensive loss for the year is attributable to:  Owners of the Company  (92,817,371) (45,344,496)  (92,817,371) (44,874,729)  (92,817,371) (44,874,729)  (92,817,371) (44,874,729)  Loss per share attributable to the owners of the Company:				
Fair value gains on investments in financial assets  Other comprehensive income for the year, net of tax  - 469,767  Total comprehensive loss for the year  Loss for the year is attributable to:  Owners of the Company  Total comprehensive loss for the year is attributable to:  Owners of the Company  Total comprehensive loss for the year is attributable to:  Owners of the Company  (92,817,371)  (44,874,729)  (92,817,371)  (44,874,729)  (92,817,371)  (44,874,729)  Loss per share attributable to the owners of the Company:	Other comprehensive income			
Other comprehensive income for the year, net of tax  - 469,767  Total comprehensive loss for the year  Loss for the year is attributable to:  Owners of the Company  Total comprehensive loss for the year is attributable to:  Owners of the Company  Total comprehensive loss for the year is attributable to:  Owners of the Company  (92,817,371)  (45,344,496)  (92,817,371)  (44,874,729)  (92,817,371)  (44,874,729)  Loss per share attributable to the owners of the Company:	Items that will not be reclassified subsequently to profit or loss:			
Total comprehensive loss for the year  Loss for the year is attributable to:  Owners of the Company  Total comprehensive loss for the year is attributable to:  Owners of the Company  Total comprehensive loss for the year is attributable to:  Owners of the Company  (92,817,371)  (44,874,729)  (92,817,371)  (44,874,729)  Loss per share attributable to the owners of the Company:	Fair value gains on investments in financial assets		-	469,767
Loss for the year is attributable to:  Owners of the Company  23 (92,817,371) (45,344,496)  (92,817,371) (45,344,496)  Total comprehensive loss for the year is attributable to:  Owners of the Company  (92,817,371) (44,874,729)  Loss per share attributable to the owners of the Company:	Other comprehensive income for the year, net of tax		-	469,767
Owners of the Company       23       (92,817,371)       (45,344,496)         Total comprehensive loss for the year is attributable to:       (92,817,371)       (44,874,729)         Owners of the Company       (92,817,371)       (44,874,729)         Loss per share attributable to the owners of the Company:       (92,817,371)       (44,874,729)	Total comprehensive loss for the year		(92,817,371)	(44,874,729)
Owners of the Company       23       (92,817,371)       (45,344,496)         Total comprehensive loss for the year is attributable to:       (92,817,371)       (44,874,729)         Owners of the Company       (92,817,371)       (44,874,729)         Loss per share attributable to the owners of the Company:       (92,817,371)       (44,874,729)	Locs for the year is attributable to:			
Total comprehensive loss for the year is attributable to:  Owners of the Company  (92,817,371) (45,344,496)  (92,817,371) (44,874,729)  (92,817,371) (44,874,729)  Loss per share attributable to the owners of the Company:		23	(02 917 371)	(45 344 496)
Total comprehensive loss for the year is attributable to:  Owners of the Company  (92,817,371) (44,874,729)  (92,817,371) (44,874,729)  Loss per share attributable to the owners of the Company:	Owners of the Company			
Owners of the Company       (92,817,371)       (44,874,729)         Loss per share attributable to the owners of the Company:       (92,817,371)       (44,874,729)			(72,017,071)	(43,044,470)
Loss per share attributable to the owners of the Company:	Total comprehensive loss for the year is attributable to:			
Loss per share attributable to the owners of the Company:	Owners of the Company		(92,817,371)	(44,874,729)
			(92,817,371)	(44,874,729)
- Basic and diluted loss per share (cents) 14 (26.40) (14.15)	Loss per share attributable to the owners of the Company:			
	- Basic and diluted loss per share (cents)	14	(26.40)	(14.15)

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, 2022

	Note	2022 US\$	2021 US\$
Assets			
Current assets			
Cash and cash equivalents	15	44,631,293	118,193,177
Current tax receivable	13	6,299,286	4,972,898
Receivables	16	257,668	565,286
Prepayments	17	8,720,195	14,386,155
Total current assets		59,908,442	138,117,516
Non-current assets			
Plant and equipment		28,082	23,259
Right-of-use asset		-	93,852
Prepayments	18	110,295	174,541
Total non-current assets		138,377	291,652
Total assets		60,046,819	138,409,168
Liabilities			
Current liabilities			
Payables	19	11,445,498	2,501,518
Lease liabilities		-	112,965
Provisions	20	596,203	492,002
Total current liabilities		12,041,701	3,106,485
Non-current liabilities			
Provisions	21	27,974	16,915
Total non-current liabilities		27,974	16,915
Total liabilities		12,069,675	3,123,400
Net assets		47,977,144	135,285,768
Equity			
Contributed equity	22	235,277,217	234,147,526
Pre-funded warrants	22	-	-
Accumulated losses	23	(216,941,353)	(124,123,982)
Reserves	23	29,641,280	25,262,224
Total equity		47,977,144	135,285,768

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, 2022

	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, 2020		113,852,364	-	3,116,080	551,409	5,827,605	(78,779,486)	44,567,972
Fair value gains on investments in financial assets*	23	-	-	-	469,767	-	-	469,767
Loss for the year*		-	-	-	-	-	(45,344,496)	(45,344,496)
Total comprehensive income and expense for the period		-	-	-	469,767	-	(45,344,496)	(44,874,729)
Recognition of share-based payment	23	-	-	3,897,638	-	-	-	3,897,638
Issue of ordinary shares on the exercise of options	22	3,271,542	-	(3,271,542)	_	-	-	-
Issue of ordinary shares and pre-funded warrants, net of issuance costs \$10,126,959	22	105,477,591	11,546,029	-	-	-	-	117,023,620
Issuance of ordinary shares and pre-funded warrants net of issuance costs \$1,099,412	22	11,546,029	(11,546,029)	-	-	_	-	_
Exchange on conversion	23	-	-	345,474	64,235	14,261,558	-	14,671,267
Balance at June 30, 2021		234,147,526	-	4,087,650	1,085,411	20,089,163	(124,123,982)	135,285,768
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	23	-	-	5,251,572	-	-	-	5,251,572
Issue of ordinary shares on the exercise of options	22	1,129,691	-	(872,516)	-	-	-	257,175
Balance at June 30, 2022		235,277,217	-	8,466,706	1,085,411	20,089,163	(216,941,353)	47,977,144

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

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

# Consolidated Statement of Cash Flows

#### For the year ended June 30, 2022

Note	2022 US\$	2021 US\$
Cash flows from operating activities		
Interest received	216,422	390,128
Royalty and license income received	90,683	103,031
Grant and other income	455,807	26,949
Payment of lease interest	(5,920)	(5,782)
Payments to suppliers, employees and for research & development and intellectual property costs (inclusive of GST)	(77,064,842)	(51,894,593)
Research and development tax incentive scheme credit received	4,972,898	5,834,100
Net cash flows used in operating activities 26	(71,334,952)	(45,546,167)
Cash flows from investing activities		
Cash received on disposal of financial asset	_	669,184
Purchase of plant and equipment	(16,910)	(12,702)
Net cash flows (used in)/provided by investing activities	(16,910)	656,482
Cash flows from financing activities		
Payment of lease liabilities	(85,578)	(87,373)
Net proceeds on issue of shares	_	105,477,591
Net proceeds on issuance of pre-funded warrants	_	11,546,029
Cash received for ordinary shares issued on exercise of options 22	257,175	=
Net cash flows provided by financing activities	171,597	116,936,247
Net (decrease)/increase in cash and cash equivalents	(71,180,265)	72,046,562
Effects of exchange rate changes on the balance of cash held in foreign currencies	(2,381,619)	3,495,757
Cash and cash equivalents at beginning of year	118,193,177	42,650,858
Cash and cash equivalents at the end of the year 15	44,631,293	118,193,117

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

#### 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 30, 2022.

#### **GOING CONCERN**

For the year ended June 30, 2022, the Group incurred a loss after income tax of \$92,817,371 (2021: \$45,344,496), and had net cash outflows from operating activities of \$71,334,952 (2021: \$45,546,167). As at June 30, 2022, the Group had cash and cash equivalents of \$44,631,293 (2021: \$118,193,177), current assets of \$59,908,442 (2021: \$138,117,516) and was in a net current asset position of \$47,866,741 (2021: \$135,011,031).

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.

Subsequent to June 30, 2022, on August 12, 2022, the Group entered a Development Funding Agreement ('Agreement') with Ocelot SPV LP ('Investor'), an affiliate of Carlyle and Abingworth, pursuant to which Investor has committed to provide Opthea \$120 million in funding which may be increased up to \$170 million at the Investor's option. Of this funding, \$50 million will be received by the Group in September 2022. Concurrently with the execution of the Agreement, the Group entered into binding commitments for the private placement of ordinary shares for aggregate gross proceeds of approximately \$90 million (the 'PIPE'). The PIPE consists of two tranches, of which the first tranche of AU\$60.7 million (US\$41.9 million) was received on August 24, 2022. The second tranche of \$47.5 million, which is subject to shareholder approval, is expected to be issued and received in September 2022. See Note 33, Events after the balance sheet date, for further information.

The Directors and management have considered the cash flow forecasts including the funding requirements of the business as well as the funding raised through the Agreement and PIPE. 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 Agreement 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.

#### 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. During 2021 the Group's operations continued to move further towards being US\$ denominated and several other factors during the period also contributed to the Group changing its functional currency during the year, such as the completion of US initial public offering (IPO) and the NASDAQ listing in October 2020, opening a US subsidiary in May 2021 for the planned expansion into the US, and expanding the Board of Directors with the appointment of now five US-based Directors. A significant element in the Group's assessment to change the functional currency resulted from the significant increase in expenses denominated in US dollars relating to advanced clinical trials since the commencement of Phase 3 trials in March 2021. These changes, as well as the fact that the Group's principal source of financing is now the US capital market and all of the Group's budgeting and planning is conducted solely in US dollars led to the Directors determining that US dollar (US\$) best represents the currency of the primary economic environment in which the entity now operates. Accordingly, the Group changed its functional currency from Australian dollar (AU\$) to US dollar (US\$) effective January 1, 2021.

#### PRESENTATION CURRENCY

Following the change in functional currency, the Group changed its presentation currency from Australian dollars (A\$) to US\$ in 2021. The change in presentation currency was made to better reflect the Group's business activities and to enhance access to US capital markets. Prior to the change, the Group reported its financial statements in Australian dollars (A\$).

A change in presentation currency is a change in accounting policy which was accounted for retrospectively during 2021. In making this change in presentation currency, the Group followed the requirements set out in IAS 21 *The Effects of Changes in Foreign Exchange Rates*. As required by IAS 21, the consolidated statement of profit or loss and other comprehensive income and the consolidated statement of cash flows for each period were translated into the presentation currency using the average exchange rates prevailing during each reporting period. All assets and liabilities were translated using the exchange rates prevailing at the consolidated statement of financial position dates. Shareholders' equity transactions were translated using the rates of exchange in effect as of the dates of various capital transactions. All resulting exchange differences arising from the translation were included as a separate component of other comprehensive income. All comparative financial information were restated to reflect the Group's results as if they had been historically reported in US\$ and the effect on the consolidated financial statements resulted in an addition to the foreign currency translation reserve of US\$14.3 million.

#### CHANGE IN PRESENTATION OF OTHER INCOME

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.

#### 3. Summary of accounting policies (cont.)

#### 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.

#### 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.

#### 3. Summary of accounting policies (cont.)

#### 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.

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.

#### PLANT AND EQUIPMENT

Plant and equipment are 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.

#### 3. Summary of accounting policies (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, 2022 and 2021, 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 fulfilled (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.

#### 3. Summary of accounting policies (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, 2022 and 2021, 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 AU\$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*.

#### 3. Summary of accounting policies (cont.)

#### 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.

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.

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, 2022 and 2021, 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, 2022 and 2021.

#### **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;
- 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, 2022 and 2021, the Group has recognized an R&D tax incentive receivable of \$6 million and \$5 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, 2022 and 2021 is based on the legislation as currently enacted as at June 30, 2022 and 2021, 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.

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

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.

#### 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

#### 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 30. 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 include:

- AASB 2020-8 Amendments to Australian Accounting Standards Interest Rate Benchmark Reform;
- AASB 2021-3 Amendments to Australian Accounting Standards Covid-19 Rent Concessions beyond 30 June 2021;
- AASB 2020-3 Amendments to Australian Accounting Standards Annual Improvements 2018-2020 and Other amendments: and
- AASB 2021-7 Amendment to Australian Accounting Standards Effective Date of Amendments to AASB 10 and AASB 128 and Editorial Corrections.

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

### NEW AND REVISED AUSTRALIAN ACCOUNTING STANDARDS AND INTERPRETATIONS ON ISSUE BUT NOT YET EFFECTIVE

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

Standard/amendment	Effective for annual reporting periods beginning on or after
AASB 2020-1 Amendments to Australian Accounting Standards – Classification of Liabilities as Current or Non-current and AASB 2020-6 Amendments to Australian Accounting Standards – Classification of Liabilities as Current and Non-current - Deferral of Effective Dated	January 1, 2023 -
AASB 2020-3 Amendments to Australian Accounting Standards – Disclosure of Accounting Policies and Definition of Accounting Estimates	January 1, 2023
AASB 2020-3 Amendments to Australian Accounting Standards – Annual Improvements 2018-2020 and Other Amendments	January 1, 2022
AASB 2022-1 Amendments to Australian Accounting Standards – Initial Application of AASB 17 and AASB 9 – Comparative Information	January 1 2023
AASB 2021-5 Amendments to Australian Accounting Standards – Deferred tax related to Assets and Liabilities arising from a Single Transaction	January 1 2023
AASB 2020-3 Amendments to Australian Accounting Standards – Annual Improvements 2018-2020 and Other Amendments	January 1, 2022
In addition, at the date of authorization of the financial statements the following IASB St Committee Interpretations were on issue but not yet effective, but for which Australian Interpretations have not yet been issued:	
Editorial corrections	
IFRS 9 Financial Instruments: Disclosures	January 1, 2022

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 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 \$90,683 (2021: \$68,613) was generated from customers based outside of Australia. The Group does not have any major customers. All property, plant and equipment are located in Australia.

#### 7. Revenue

	2022 US\$	2021 US\$
Sales-based royalties	90,683	68,613
Total revenue	90,683	68,613

#### 8. Other income

	2022 US\$	2021 US\$
Grant and other income	108,322	26,950
Total other income	108,322	26,950

#### 9. Research and development expenses

	2022 US\$	2021 US\$
Research project costs <sup>20</sup>	78,654,217	25,891,851
Total research and development expenses	78,654,217	25,891,851

<sup>20.</sup> The research project costs relate to the research programs in respect to the treatment of eye diseases by OPT-302.

#### 10. Expenses

	2022 US\$	2021 US\$
Administrative expenses		
Employee benefits expenses:		
Salaries and fees	2,931,243	1,794,840
Cash bonuses	376,649	479,501
Superannuation	171,899	188,543
Share-based payments expense	5,251,572	3,897,638
Total employee benefits expense	8,731,363	6,360,522
Other expenses:		
Insurance	4,205,106	4,419,433
Investor relations costs	328,026	285,071
Audit and accounting	496,652	647,549
Travel expenses	13,616	1,459
Payroll tax	172,884	18,766
Legal fees	1,252,014	83,605
Advisory fees	156,978	393,843
Consultancy costs	1,619,824	367,070
Other expenses	846,098	714,328
Total other expenses	9,091,198	6,931,124
Depreciation of:		
Equipment and furniture	11,917	15,012
Right-of-use asset	66,465	91,656
Total depreciation expense	78,382	106,668
Loss on disposal of non-current assets	169	1,434
Total administrative expenses	17,901,112	13,399,748

#### 11. Finance Income

	2022 US\$	2021 US\$
Interest income	235,468	372,001
	235,468	372,001

#### 12. Net foreign exchange loss

	2022 US\$	2021 US\$
Net foreign exchange losses	(2,813,993)	(11,011,961)
	(2,813,993)	(11,011,961)

Exchange differences arising on the translation of monetary items are recognized in the Statement Profit and Loss and other Comprehensive Income, except where deferred in equity as a qualifying cash flow or net investment hedge. After the Company's US IPO in fiscal year 2021 where the Company raised US\$128 million, the Company entered into an Australian dollar denominated term deposit worth US\$100 million (AU\$141.9 million), that matured on February 3, 2021. The Company simultaneously entered into a foreign currency exchange contract under which the term deposit converted back to US dollars at effectively the same foreign exchange rate as when the term deposit was entered into. As the Group's functional currency was the Australian dollar (AU\$) until December 31, 2020, the Group recorded a foreign exchange loss of US\$9 million in relation to this transaction during the year ended June 30, 2021.

#### 13. Income tax

	2022 US\$	2021 US\$
(a) Income tax benefit		
The major components of income tax benefit are:		
Statement of Profit or Loss and Other Comprehensive Income		
Current tax		
Current income tax credit	6,299,286	4,938,846
	6,299,286	4,938,846
Deferred tax		
In respect of the current year	_	_
Total income tax benefit recognized in the Statement of Profit or Loss and Other Comprehensive Income	6,299,286	4,938,846
(b) Current tax receivable		
Research and Development Tax Incentive Credit receivable	6,299,286	4,972,898

#### 13. Income tax (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:

	2022 US\$	2021 US\$
Accounting loss before tax	(99,116,657)	(50,283,342)
At the Company's statutory income tax rate of 30% (2021: 30%)	29,734,997	15,085,003
R&D tax incentive on eligible expenses	6,299,286	4,938,846
Non-deductible R&D expenditure	(4,344,335)	(3,420,951)
Other non-deductible expenses – share-based payment expense	(1,575,472)	(1,169,291)
Amount of temporary differences and carried forward tax losses not recognized	(23,815,190)	(10,494,761)
Income tax benefit reported in the Statement of Profit or Loss and Other Comprehensive Income	6,299,286	4,938,846
(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)	(17,085)	(2,344,514)
	(17,085)	(2,344,514)
Deferred tax assets related to temporary differences:		
Recognition of tax losses	_	1,508,764
Accrued expenses and other liabilities	198,607	205,458
Employee provisions	161,159	152,675
Other miscellaneous items	306,531	477,617
	666,297	2,344,514
Net deferred tax assets	649,212	
Less: temporary differences not recognized	(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 (2021: \$nil).

#### (f) Carry forward unrecognized tax losses

The Group had income tax losses of \$37,717,792 and capital losses of \$412,122 at year end (2021: income tax losses of \$20,846,641 and capital losses of \$672,934) 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.

#### 13. Income tax (cont.)

#### (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 AU\$227,371 (2021: 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.

#### 14. Earnings per share

	2022 US\$	2021 US\$
The following reflects the income used in the basic and diluted earnings per share computations:		
(a) Earnings used in calculating earnings per share		
Net loss attributable to ordinary equity holders of the parent	(92,817,371)	(45,344,496)
(b) Weighted average number of shares		
Weighted average number of ordinary shares on issue for basic earnings per share	351,560,199	320,432,814
Effect of dilution:		
Share options	-	-
Weighted average number of ordinary shares adjusted for the effect of dilution	351,560,199	320,432,814
Loss per share (basic and diluted in cents)	(26.40)	(14.15)

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

Diluted earnings per share is calculated as net 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.

A total number of 22,988,000 options/rights outstanding at June 30, 2022 (2021: 16,644,000) and 925,000 ADS options (2021: nil) 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:

	2022 No.	2021 No.
NED Plan	14,000,000	10,000,000
LTIP	7,388,000	6,644,000
	21,388,000	16,644,000

#### 14. Earnings per share (cont.)

#### Performance Rights

These rights related to the following option plans:

	2022 No.	2021 No.
NED Plan	-	=
LTIP	1,600,000	_
	1,600,000	_

#### **ADS** options

These rights related to the following option plans:

	2022 No.	2021 No.
NED Plan	-	-
LTIP	925,000	_
	925,000	_

As at June 30, 2022, 12,857,589 outstanding options and rights were exercisable as of that date (2021: 11,394,000). As at June 30, 2022, Nil outstanding ADS options were exercisable as of that date.

#### 15. Current assets - cash and cash equivalents

	2022 US\$	2021 US\$
Cash at bank and in hand	11,853,883	15,538,510
Short-term deposits	32,777,410	102,654,667
Total cash and cash equivalents	44,631,293	118,193,177

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 0.43% (2021: 0.24%).

#### 16. Current assets - receivables

	2022 US\$	2021 US\$
Interest receivable	56,952	37,905
GST receivable	157,060	136,239
Other receivable	43,656	391,142
Total current receivables	257,668	565,286

The GST and other receivables are non-interest bearing. There were no receivables with a material expected credit loss recorded during the financial year (2021: nil).

#### 17. Current assets - prepayments

	2022 US\$	2021 US\$
R&D Contract Research Organization	7,428,599	12,551,398
Insurance	1,086,847	1,820,059
Other prepayments	204,749	14,698
Total current prepayments	8,720,195	14,386,155

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 18.

#### 18. Non-current assets - prepayments

	2022 US\$	2021 US\$
Insurance	110,295	174,541
Total non-current prepayments	110,295	174,541

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.

#### 19. Current liabilities - payables

	2022 US\$	2021 US\$
Creditors (unsecured)	11,402,164	2,417,719
Payroll related tax liability	43,334	83,799
Total current payables	11,445,498	2,501,518

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

#### 20. Current liabilities - provisions

	2022 US\$	2021 US\$
Annual leave	383,220	289,043
Long service leave	212,983	202,959
Total current provisions	596,203	492,002

#### 21. Non-current liabilities - provisions

	2022 US\$	2021 US\$
Long service leave	27,974	16,915

#### 22. Contributed Equity

	2022 US\$	2021 US\$
(a) Ordinary shares		
Issued and fully paid at June 30	235,277,217	234,147,526
Movement in ordinary shares:		
Opening balance	234,147,526	113,852,364
Issue of shares on exercise of options granted under the LTIP	1,129,691	3,271,542
Issue of shares on NASDAQ listing net of issuance cost \$10,126,959	-	105,477,591
Issue of shares on exercise of warrants net of issuance cost \$1,099,412	-	11,546,029
	235,277,217	234,147,526
Ordinary shares on issue:	No:	No:
Opening balance	351,003,541	269,157,769
Issue of shares on exercise of options granted under the LTIP	1,149,001	5,845,804
Issue of shares on NASDAQ listing	-	68,506,400
Issue of shares on exercise of pre-funded warrants	-	7,493,568
	352,152,542	351,003,541

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, 2022 amounted to \$235,277,217 (352,152,542 fully paid ordinary shares) net of share issue costs and tax. During the year ended June 30, 2021 the Company issued 68,506,400 ordinary shares on NASDAQ listing for net proceeds of \$105,477,591 as well as issued 7,493,568 pre-funded warrants for net proceeds of \$11,546,029.

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 25 for 500,000 options and April 26 for 500,000 options.

At June 30, 2021, the Company had 3,250,000 Non-Executive Director options that remain unexercised with expiry of November 2022 for 1,500,000 options, October 2024 for 1,000,000 options and January 2025 for 750,000 options.

#### 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 8,400,000 options/rights over ordinary shares and 925,000 ADS options under these plans during the year ended June 30, 2022 (Note 30). 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). The company granted 7,000,000 options over ordinary shares under these plans during the year ended June 30, 2021 (Note 30). These options had a weighted average fair value at their grant date of \$1.03 per option. During the year ended June 30, 2021 8,400,000 options granted under the LTIP and NED Plan were exercised for \$3,271,542.

#### 22. Contributed Equity (cont.)

	2022 US\$	2021 US\$
(b) Pre-funded warrants		
Movement in pre-funded warrants:		
Opening balance	-	-
Issue of pre-funded warrants in a US Initial public offering	-	12,645,441
Cost of issue of pre-funded warrants	-	(1,099,412)
Issue of shares on exercise of pre-funded warrants	-	(11,546,029)
	-	-

Pre-funded warrants on issue:	No:	No:
Opening balance	-	-
Issue of pre-funded warrants in a US Initial public offering	-	7,493,600
Exercise of pre-funded warrants	-	(7,493,568)
Forfeiture on exercise	-	(32)
	-	-

The Company issued 7,493,600 pre-funded warrants for US\$11,546,029 net of issue costs in respect of the US initial public offering in fiscal year 2021. The pre-funded warrants were unquoted, having no voting or dividend rights and are exercisable to ADS's at an exercise price of US\$0.00001 per pre-funded warrant on a one for one basis with no expiry date. On June 21, 2021 all pre-funded warrants were exercised, converting to ADS's.

#### (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.

#### 23. Accumulated losses and reserves

	2022 US\$	2021 US\$
(a) Movements in accumulated losses were as follows:		
Balance at July 1	(124,123,982)	(78,779,486)
Net loss for the period	(92,817,371)	(45,344,496)
Balance at June 30	(216,941,353)	(124,123,982)
(b) Reserves		
Fair value of investments reserve (i)	1,085,411	1,085,411
Share-based payments reserve (ii)	8,466,706	4,087,650
Foreign translation reserve (iii)	20,089,163	20,089,163
Total reserves	29,641,280	25,262,224
(i) Movement in fair value of investments reserve:		
Opening balance	1,085,411	551,409
Fair value gains on investments in financial assets	-	469,767
Exchange on translation	-	64,235
Closing balance	1,085,411	1,085,411
(ii) Movement in share-based payments reserve:		
Opening balance	4,087,650	3,116,080
Share-based payments expense	5,251,572	3,897,638
Exercise of options	(872,516)	(3,271,542)
Exchange on translation	-	345,474
Closing balance	8,466,706	4,087,650
(iii) Movement in Foreign translation reserve:		
Opening balance	20,089,163	5,827,605
Gain/loss on translation	-	14,261,558
Closing balance	20,089,163	20,089,163

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

#### Fair value of investments reserve

This reserve records fair value changes on listed investments.

#### Share-based payment reserve

This reserve is used to record the value of equity benefits provided to executives and employees as part of their remuneration.

#### Foreign currency translation reserve

The reserve records the value of foreign currency movements on translation of financial statements from AU\$ to US\$.

#### 24. 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 does not have any borrowings (2021: nil).

The following sensitivity analysis (an annual effect) is based on the interest rate risk exposures at June 30, 2022 and 2021.

At June 30, 2022, if interest rates moved, with all variables held constant, post tax (loss)/profit and equity would have been affected as illustrated in the following table:

	Post tax (loss)/profit illipact	
Judgments of reasonably possible movements	2022 US\$	2021 US\$
+ 0.50% (50 basis points) (2020: + 0.50%)	114,859	359,442
- 0.50% (50 basis points) (2020: - 0.50%)	(114,859)	(359,442)

The post tax figures include an offset for unrecognized tax losses (bringing the tax effect to nil) for the year ended June 30, 2022 (2021: 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'.

## 24. Financial risk management objectives and policies (cont.)

• 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.

		Consolidat	ted	
2022	AUD 2021 US\$	EURO 2021 US\$	GBP 2021 US\$	CAD 2021 US\$
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)
2021	AUD 2021 US\$	EURO 2021 US\$	GBP 2021 US\$	CAD 2021 US\$
Financial assets				
Cash	35,646,457	_	_	_
Receivables	5,513,541	_	=	-
Financial liabilities				
Payables	(1,276,164)	(41,872)	=	(1,290)
Other financial liabilities			=	
Net exposure	39,883,834	(41,872)	_	(1,290)

#### 24. Financial risk management objectives and policies (cont.)

The following sensitivity is based on the foreign currency risk exposures in existence at June 30, 2022 and 2021.

At June 30, 2022 and 2021, 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:

	Post tax (loss)/profit impact			
Judgments of reasonably possible movements	2022 US\$	2021 US\$		
Consolidated				
AUD/USD +10% (2021: +10%)	(2,119,834)	(2,538,062)		
AUD/USD -10% (2021: -10%)	2,590,908	3,102,076		

The reasonably possible movements at June 30, 2022 are lower than at June 30, 2021 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 OPT-302 for the treatment of wet AMD for each calendar quarter. Refer to Subsequent event Note 33 for further information on the transaction.

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

## 25. Related party disclosures

## (a) Subsidiaries

		Parent equity % equity interest			
Name of company	2022	2021 %			
Vegenics Pty Ltd <sup>21</sup>	100	100			
Opthea US Inc <sup>22</sup>	100	100			

#### (b) Transactions with related parties

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

<sup>21.</sup> Opthea Limited is the ultimate parent entity. Vegenics Pty Ltd is incorporated in Australia and has the same financial year as Opthea Limited.

<sup>22.</sup> 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.

### 26. Cash flow statement reconciliation

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

	2022 US\$	2021 US\$
Cash at bank and in hand (Note 15)	44,631,293	118,193,177
	44,631,293	118,193,177
(b) Reconciliation of net loss after tax to net cash flows from operations		
Net loss for the year	(92,817,371)	(45,344,496)
Adjustments for:		
Income tax benefit recognized in profit or loss	(6,299,286)	(4,938,846)
Net loss on disposal of non-current assets	169	_
Depreciation of non-current assets	11,917	15,012
Depreciation of right-of-use asset	66,465	91,656
Share-based payments expense	5,251,572	3,897,638
Net exchange differences	2,813,993	11,011,961
	1,844,830	10,077,421
Changes in working capital:		
Payables	8,511,607	(1,552,443)
Receivables	307,618	(369,712)
Prepayments	5,730,207	(14,231,546)
Provisions	115,259	40,510
Net cash flows used in operating activities before tax	(76,307,850)	(51,380,266)
R&D tax incentive received	4,972,898	5,834,099
Net cash flows used in operating activities	(71,334,952)	(45,546,167)
	2022 US\$	2021 US\$
(c) Reconciliation of borrowings arising from financing activities		
Balance at July 1	93,852	167,460
Payment of lease liabilities	(85,578)	(87,373)
Exchange on translation	(8,274)	13,765
Balance at June 30	-	93,852

#### 27. 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:

	2022 US\$	2021 US\$
Within one year	39,947,900	26,377,778
After one year but not more than five years	8,007,202	2,347,060
After more than five years	45,000	_
	48,000,102	28,724,838

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:

	2022 US\$	2021 US\$
Within one year	507,874	=
After one year but not more than five years	_	-
After more than five years	_	-
	507,874	_

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

#### 28. 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 (2021: \$nil) and those which could become payable in more than one year total \$11,512,675 (2021: \$11,548,205).

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, 2022 in respect of a rental deposit for its office premises of \$39,478 (2021: \$43,000).

#### 29. Key management personnel

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

	2022 US\$	2021 US\$
Short-term employee benefits	1,555,658	1,099,081
Post-employment benefits	56,105	79,550
Share-based payments expense	4,664,767	3,897,638
Total compensation	6,276,530	5,076,269

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.

### 30. 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:

	2022 US\$	2021 US\$
Expense arising from equity-settled share-based payment transactions:		
Director and employee services received	5,251,572	3,897,638

### (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.

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

## 30. Share-based payments (cont.)

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 - employees FY2016	March 31, 2016	\$0.18	\$0.37	January 1, 2022	January 1, 2017
LTIP - employees FY2018	August 23, 2017	\$0.26	\$0.92	January 1, 2023	June 30, 2018
LTIP - employees FY2019	April 3, 2019	\$0.18	\$0.608	April 3, 2023	April 3, 2021
LTIP - employees FY2022	October 19, 2021	\$0.955	\$0.00	October 18, 2031	October 19, 2021
LTIP - employees FY2022	October 19, 2021	\$0.955	\$0.00	October 18, 2031	October 19, 2022
LTIP - employees FY2022	October 19, 2021	\$0.955	\$0.00	October 18, 2031	October 19, 2023
LTIP - employees FY2022	October 19, 2021	\$0.955	\$0.00	October 18, 2031	January 31, 2023
LTIP - employees FY2022	October 19, 2021	\$0.955	\$0.00	October 18, 2031	November 30, 2022
LTIP - employees FY2022	October 19, 2021	\$0.955	\$0.00	October 18, 2031	April 30, 2023
LTIP - employees FY2022	October 19, 2021	\$0.955	\$0.00	October 18, 2031	April 30, 2023
LTIP - employees FY2022	October 19, 2021	\$0.955	\$0.00	October 18, 2031	September 30, 2024
LTIP - employees FY2022	October 19, 2021	\$0.526	\$0.948	October 18, 2025	October 19, 2021
LTIP - employees FY2022	October 19, 2021	\$0.526	\$0.948	October 18, 2025	October 19, 2022
LTIP - employees FY2022	October 19, 2021	\$0.526	\$0.948	October 18, 2025	October 19, 2023
LTIP - employees FY2022	October 19, 2021	\$0.526	\$0.948	October 18, 2025	October 19, 2024
LTIP - employees FY2022	June 6, 2022	\$0.553	\$1.46	June 5, 2032	June 6, 2022
LTIP - employees FY2022	June 6, 2022	\$0.553	\$1.46	June 5, 2032	June 6, 2023
LTIP - employees FY2022	June 6, 2022	\$0.553	\$1.46	June 5, 2032	June 6, 2024
LTIP - employees FY2022	June 6, 2022	\$0.553	\$1.46	June 5, 2032	June 6, 2025
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
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

## 30. Share-based payments (cont.)

Options/Rights series	Grant date	Grant date fair value US\$	Exercise price US\$	Expiry date	Vesting date
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

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 - employees FY2016	\$0.54	\$0.37	\$0.18	65%	5 years	0%	2.09%	Binomial
LTIP - employees FY2018	\$0.34	\$0.92	\$0.26	66%	5 years	0%	2.09%	Binomial
LTIP - employees FY2019	\$0.48	\$0.608	\$0.18	57%	4 years	0%	2.04%	Binomial
LTIP - employees FY2022	\$0.955	\$0.948	\$0.526	74.78%	4 years	0%	0.25%	Binomial
LTIP - employees FY2022	\$0.955	\$nil	\$0.955	n/a	10 years	0%	n/a	n/a
LTIP - employees FY2022	\$0.901	\$1.46	\$0.553	75%	6.5 years	0%	3.4%	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

### 30. Share-based payments (cont.)

### 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

#### (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, 2022		June 30, 2021	
	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	16,644,000	0.50	18,044,000	0.50
Granted during the year:				
To employees and directors under the LTIP and NED Plan	8,400,000	0.77	7,000,000	2.21
Exercised during the year	(2,056,000)	0.58	(8,400,000)	0.38
Expired during the year	-	-	-	
Balance at end of year	22,988,000	1.16	16,644,000	1,28
Exercisable at end of year	12,857,589	0.97	11,394,000	0.86

The share options outstanding at the end of the year had a weighted average exercise price of \$0.97 (2021: \$0.86) and a weighted average remaining contractual life of 567 days (2021: 628 days).

## 30. Share-based payments (cont.)

## (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, 2022		June 30, 2022 June 30, 20	
	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	-	-	=	-
Granted during the year:				
To employees and directors under the LTIP and NED Plan	925,000	6.75	_	-
Exercised during the year	-	-	_	-
Expired during the year	-	-	_	_
Balance at end of year	925,000	6.75	=	
Exercisable at end of year	-	=	=	

## 31. Net tangible asset backing

	2022 US\$	2021 US\$
Net tangible assets (including Right-of-use assets)	0.20	0.58

## 32. Auditor's remuneration

The auditor of Opthea Limited is Deloitte Touche Tohmatsu.

	2022 A\$	2021 A\$
Deloitte and related networks firms:		
Audit or review of the financial report of the entity and any other entity in the consolidated group	295,000	408,660
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	45,000
	466,171	453,660

#### 33. Events after the balance sheet date

#### DEVELOPMENT AGREEMENT AND PIPE FUNDING

On August 12, 2022 (the "Effective Date"), Opthea Limited ("Opthea") entered into a Development Funding Agreement (the "Agreement") with Ocelot SPV LP ("Investor"), an affiliate of Carlyle and Abingworth, working together with Carlyle and Abingworth's recently formed development company Launch Therapeutics, pursuant to which 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 the Agreement, Investor has committed to provide Opthea US\$120 million in funding which may be increased up to US\$170 million at Investor's option, of which US\$50 million will be paid shortly after Opthea receives the proceeds from the first tranche of the PIPE (as defined below), with the remainder being funded in two additional tranches to be paid on December 31, 2022 and December 31, 2023, respectively. Pursuant to the Agreement, Opthea will be required to use commercially reasonable efforts to develop OPT-302 for the treatment of wet AMD in accordance with the Agreement, including pursuant to certain development timelines set forth therein.

In return, Opthea will pay to Investor (1) upon the first to occur of 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 payments payable over a six-year period thereafter, and (2) variable payments equal to 7% of net sales of OPT-302 for the treatment of wet AMD for each calendar quarter.

At the time that Investor receives an aggregate of four times the funding provided (US\$680 million if Investor funds the full US\$170 million under the Agreement) (the "Cap"), Opthea's payment obligations under the Agreement will be fully satisfied. Opthea has the option to satisfy its payment obligations to Investor upon Regulatory Approval or a change of control of Opthea by paying an amount equal to the present value of the remaining payments payable to Investor subject to a mid-single-digit discount rate. Opthea also has an option to buy out the remaining payments at any time by paying an amount equal to the remaining payments due subject to a proposed discount rate, which Investor may accept or reject. Upon a change of control of Opthea, an acceleration payment of a specified multiple of the funding provided is payable, net of payments already made to Investor and creditable against future payments to Investor.

Opthea will grant Investor a security interest in all of its assets (other than intellectual property not related to OPT-302). The security interest will terminate when Investor receives payments and/or change of control acceleration payments equal to two times the funding provided or upon certain terminations of the Agreement (the "Release Date"). The Agreement also includes customary representations and warranties and covenants, including certain negative covenants regarding limitations on incurrence of indebtedness, liens, investments, restricted payments, sales of assets, and royalty sales. The negative covenants will terminate upon the Release Date.

The Agreement terminates upon the payment of all payments owing to Investor, unless earlier terminated by Investor if:

- Opthea fails to comply with certain covenants and agreements set forth in the Agreement, including failure to make required payments or develop OPT-302 as set forth in the Agreement;
- Opthea suffers a material adverse event;
- there is a material adverse patent impact on Opthea's intellectual property covering OPT-302;
- there are certain irresolvable disagreements within the joint steering committee overseeing Opthea's development of OPT-302;
- the security interests of Opthea are invalidated or terminated other than as set forth in the Agreement; or
- any Phase 3 clinical trial of OPT-302 is completed or terminated and (1) the primary endpoint is not met or (2) Investor reasonably determines that the results of any such trial do not support regulatory approval.

The Agreement may also be earlier terminated by Opthea if Investor fails to fund as provided in the Agreement. The Agreement may be terminated by either party (i) if the other party materially breaches the Agreement ("Material Breach"), (ii) if OPT-302 fails to receive regulatory approval in the United States or European Union, (iii) upon the bankruptcy of the other party, (iv) if a serious safety concern arises in an OPT-302 clinical trial or (vi) upon a change of control of Opthea.

#### 33. Events after the balance sheet date (cont.)

In certain instances, upon the termination of the Agreement, Opthea will be obligated to pay Investor a multiple of the amounts paid to Opthea under the Agreement, including specifically,

- up to the Cap in the event that Investor terminates the agreement due to (w) failure by Opthea to comply with certain covenants and agreements set forth in the Agreement, including failure to make required payments or develop OPT-302 as set forth in the Agreement, (x) the bankruptcy of Opthea, (y) a safety concern resulting from gross negligence on the part of Opthea or due to a safety concern that was material on the Effective Date and the material data showing such safety concern was not publicly known, disclosed to Investor, or in the diligence room made available to Investor or (z) the security interests of Investor being invalidated or terminated other than as set forth in the Agreement;
- several multiples of such amounts in the event the Agreement is terminated due to Material Breach by Opthea; and
- a small multiple of such amounts in the event of certain irresolvable disagreements within the executive review committee overseeing Opthea's development of OPT-302.

In addition, if following certain events of termination of the Agreement, Opthea continues to develop OPT-302 for the treatment of wet AMD and obtains Regulatory Approval, it will make the payments to Investor as if the Agreement had not been terminated, less any payments made upon termination.

The Agreement also provides that Opthea will use reasonable best efforts to complete a private placement of its ordinary shares or American Depositary Shares ("ADS's") representing its ordinary shares (at a ratio of 8 ordinary shares per ADS) for gross proceeds of at least US\$70 million, which Opthea expects will be satisfied through the PIPE (as described below).

The Agreement also includes a minimum cash requirement, and Opthea may need to obtain additional funding to meet this requirement in the future, including prior to the expected readout of top-line results for its Phase 3 clinical trials. To the extent that Opthea raises additional capital through the sale of equity or convertible debt securities to meet this requirement, Opthea's equity holders will be diluted.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by the full text of the Agreement, a copy of which will be filed as an exhibit to Opthea's Annual Report on Form 20-F for the fiscal year ended June 30, 2022, which will be subsequently filed with the Securities and Exchange Commission.

Concurrently with the execution of the Agreement, Opthea entered into binding commitments for the private placement of ordinary shares to be issued pursuant to Regulation S under, and Section 4(a)(2) of, the Securities Act of 1933, as amended (the "Securities Act"), as the case may be, for aggregate gross proceeds of approximately US\$90 million (the "PIPE") and a price per ordinary share of AU\$1.15 (approximately US\$0.81).

The PIPE consists of two tranches. The first tranche will be for AU\$60.7 million (US\$41.9 million), or 52.8 million ordinary shares, which amount represents the amount of new ordinary shares that Opthea may currently issue without obtaining shareholder approval under ASX Listing Rules. The first tranche was receipted on August 24, 2022. Opthea will use reasonable best efforts to obtain shareholder approval to issue and consummate the second tranche, which will be for US\$47.5 million, or 59 million shares.

Opthea expects to issue a Notice of Meeting to its shareholders to convene a general meeting of shareholders expected in September 2022 to obtain shareholder approval to issue and consummate the second tranche.

The Company is still assessing the accounting treatment of this transaction.

#### APPROVAL OF ADVANCED OVERSEAS FINDING CERTIFICATE

On August 29, 2022, the Company obtained an Advanced Overseas Finding Certificate from AusIndustry for additional overseas research activities for OPT-302. This is a non-adjusting subsequent event.

Besides the above-mentioned subsequent events, no matters or circumstances 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.

## 34. 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

	2022 US\$	2021 US\$
Current assets	61,913,395	138,331,255
Non-current assets	129,015	117,110
Total assets	62,042,410	138,448,365
Current liabilities	(11,417,465)	(3,078,269)
Non-current liabilities	(27,974)	(16,916)
Total liabilities	(11,445,439)	(3,095,185)
Net assets	50,596,971	135,353,180
Issued capital	235,277,217	234,147,526
Accumulated losses	(214,377,855)	(124,112,899)
Employee equity benefits reserve	8,466,706	4,087,650
Fair value of investments reserve	1,085,411	1,085,411
Foreign currency translation reserve	20,145,492	20,145,492
Total shareholders' equity	50,596,971	135,353,180

## (b) Financial performance

	Year ended June 30, 2022 US\$	Year ended June 30, 2021 US\$
Loss of the parent entity	(90,264,957)	(45,304,268)
Other comprehensive income	-	469,767
Total comprehensive loss of the parent entity	(90,264,957)	(44,834,501)

#### 34. Parent entity information (cont.)

### (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, 2022 (2021: 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 (2021: \$nil) and those which could become payable in more than one year total \$11,512,675 (2021: \$11,548,205).

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, 2022 in respect of a rental deposit for its office premises of \$39,478 (2021: \$43,000).

## Directors' Declaration

## for the year ended June 30, 2022

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, 2022 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, 2022.

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

Jeremy Levin Chairman Opthea Limited

Melbourne August 30, 2022

# Auditor's Independence Declaration

## Deloitte.

Deloitte Touche Tohmatsu A.B.N. 74 490 121 060

Tower 2, Brookfield Place 123 St Georges Terrace Perth WA 6000 GPO Box A46 Perth WA 6837 Australia

Tel: +61 8 9365 7000

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

30 August 2022

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 2022, 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

Deloitre Tomme Tommarsu

DELOITTE TOUCHE TOHMATSU

Vincent Snijders

Partner

Chartered Accountants

Liability limited by a scheme approved under Professional Standards Legislation Member of Deloitte Asia Pacific Limited and the Deloitte organisation.

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## Independent Auditor's Report

## Deloitte.

Deloitte Touche Tohmatsu ABN 74 490 121 060

Tower 2, Brookfield Place 123 St Georges Terrace Perth WA 6000 GPO Box A46 Perth WA 6837 Australia

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

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

#### Opinion

We have audited the financial report of Opthea Limited ("Opthea" or the "Company") and its subsidiaries (the "Group"), which comprises the Consolidated Statement of Financial Position as at 30 June 2022, 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:

- giving a true and fair view of the Group's financial position as at 30 June 2022 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 Atlandards 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.

#### **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.

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#### **Key Audit Matter** How the scope of our audit responded to the Key Audit Ongoing capital funding activities and the going The Group is subject to capital raising requirements Our procedures included, but were not limited to: as it conducts its clinical trials for OPT-302, and its Obtaining an understanding of the process flows ability to raise capital is a key determinant of the and key controls associated with the preparation Group's ability to continue as a going concern. and review of management's going concern assessment and cash flow forecast. As disclosed in Notes 2 and 33 of the Financial Reviewing management's assessment of the Statements of the Group, subsequent to 30 June Group's ability to continue as a going concern. 2022, on 12 August 2022, the Group entered a Analysing the cashflow forecast prepared by Development Funding Agreement ("Agreement") management, and considering the future with Ocelot SPV LP ("Investor"), pursuant to which outcome of events or conditions in the evaluation the Investor has committed to provide Opthea of management's plans for future actions, \$120 million in funding which may be increased up including: to \$170 million at the Investor's option. o Evaluating the reliability of the underlying data generated to prepare the forecast: and Concurrently with the execution of the Agreement, Determining whether there is adequate the Group entered into binding commitments for support for the assumptions underlying the private placement of ordinary shares for the forecast. aggregate gross proceeds of approximately \$90 Reading the Agreement to determine the critical million (the "PIPE"). The PIPE consists of two conditions set forth in the Agreement that must tranches, of which the first tranche of \$41.9 million be complied with by the Group, and assessing was received on 24 August 2022. The second management's ability to meet these conditions; tranche of \$47.5 million, or 59 million shares, which is subject to shareholder approval, is expected to and be issued and received in September 2022. Assessing whether a material uncertainty exists related to events or conditions that may cast significant doubt on the entity's ability to We identified that the most significant assumptions continue as a going concern. in assessing the Group's ability to continue as a going concern are: We also assessed the appropriateness of the disclosures in the Group's ability to meet the conditions Note 2 and 33 to the financial statements. set forth in the Agreement, and the Group's ability to obtain shareholder approval for the second tranche for the as these are the key determinants in the successful outcome of the Agreement and PIPE which is an assumption in the Group's cashflow forecast. We have therefore spent significant audit effort, including the time of senior members of our audit team, in assessing the appropriateness of these assumptions Our procedures included, but were not limited to: Research and development tax incentive The Group operates in the biotechnology market Assessing the design and implementation of key and is in the clinical research stage of developing a controls in relation to R&D expenditure and the molecule asset, OPT-302, for the treatment of eye preparation and review of the R&D tax incentive

calculation; and

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diseases.

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#### Key Audit Matter

The Group claims Research & Development tax incentives ("R&D tax incentives") provided by the Australian Government as disclosed in Note 4.1.

For the year ended 30 June 2022, the Group has recognised an R&D tax incentive receivable of \$6.3 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.

Management exercises significant judgement in respect of R&D tax incentives claimed by the Group including:

- Determining the accounting policy used in accounting for the R&D tax incentive.
- Assessing the eligibility of R&D activities and costs attributed to those eligible R&D activities against the rules and regulations governing the R&D tax incentive.
- Determining the estimated amounts, timing and geographical location of costs related to the projects for which R&D tax incentive applications have been approved to date.

We have therefore spent significant audit effort, including the time of senior members of our audit team, in assessing the appropriateness of these assumptions

#### How the scope of our audit responded to the Key Aud Matter

 Assessing the accounting policy adopted by the Group to account for the R&D tax incentive.

In conjunction with our R&D tax specialists we performed the following procedures:

- Obtaining an understanding of the rules and regulations governing R&D tax incentives and the basis used by the Group to recognise the incentive
- Assessing the work performed by the Group's external R&D tax advisors to understand the process for the preparation and review of the R&D tax incentive submissions.
- Assessing the competency and scope of the Group's external R&D tax advisors.
- Assessing management's documentation addressing how the Group's R&D activities satisfy the eligibility criteria outlined in the rules and regulations governing the R&D tax incentives.
- On a sample basis, inspecting R&D expenses to supporting documentation.
- Testing on a sample basis, management's apportionment of costs to these R&D activities and whether the underlying methodology used for the apportionment is consistent with the rules and regulations governing the R&D tax incentive.
- Assessing management's R&D project cost claimed for tax incentives for eligible activities, including assessing the amounts claimed, timing and geographical location of the costs.

We also assessed the appropriateness of the disclosures in Note 3, 4.1 and 13 to the financial statements.

#### Other Information

The directors are responsible for the other information. The other information comprises the information included in the Company's annual report for the year ended 30 June 2022 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.

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#### 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.
- 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.

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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 26 to 38 of the Directors' Report for the year ended 30 June 2022.

In our opinion, the Remuneration Report of Opthea Limited, for the year ended 30 June 2022 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.

Deloitre Tomme Tommarsu

DELOITTE TOUCHE TOHMATSU

Vincent Snijders

Partner

Chartered Accountants Perth, 30 August 2022

# **ASX Additional Information**

## 1. Distribution of equity securities

The number of shareholders, by size of holding, of quoted fully paid ordinary shares as at July 25, 2022 is as follows:

	Fully paid or	Fully paid ordinary shares	
Category	No. of holders	No. of shares	
1 - 1,000	2,849	1,584,740	
1,001 - 5,000	2,989	7,874,361	
5,001 - 10,000	926	7,181,679	
10,001 - 100,000	882	24,239,378	
100,001 and Over	125	311,272,384	
Total	7,816	352,152,542	
Number of shareholders holding less than a marketable parcel of shares	1,110	257,039	

## 2. Twenty largest shareholders

The names of the 20 largest holders of quoted fully paid ordinary shares and their respective holdings at July 25, 2022 are:

Rank	Name	No. of shares	% interest
1	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	104,832,480	29.77%
2	CITICORP NOMINEES PTY LIMITED	42,603,686	12.10%
3	USB NOMINEES PTY LTD	24,379,784	6.92%
4	JP MORGAN NOMINEES AUSTRALIA PTY LIMITED	21,820,567	6.20%
5	NATIONAL NOMINEES LIMITED	12,406,402	3.52%
6	BNP PARIBAS NOMS PTY LTD < DRP	11,922,174	3.39%
7	JAGEN PTY LTD	11,581,484	3.29%
8	MERRILL LYNCH (AUSTRALIA) NOMINEES PTY LIMITED	11,238,214	3.19%
9	ARMADA TRADING PTY LIMITED	5,071,967	1.44%
10	CS THIRD NOMINEES PTY LIMITED <hsbc 13="" a="" au="" c<="" cust="" ltd="" nom="" td=""><td>4,773,043</td><td>1.36%</td></hsbc>	4,773,043	1.36%
11	MS MARGARET LYNETTE HARVEY	4,000,000	1.14%
12	SAFO INVESTMENTS PTY LTD <safo a="" c<="" investment="" td=""><td>3,039,766</td><td>0.86%</td></safo>	3,039,766	0.86%
13	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED <gsco a="" c<="" customers="" td=""><td>3,000,000</td><td>0.85%</td></gsco>	3,000,000	0.85%
14	GAJA HOLDINGS	2,851,675	0.81%
15	LL FAMILY NOMINEES PTY LTD <laini a="" c<="" family="" liberman="" td=""><td>2,527,897</td><td>0.72%</td></laini>	2,527,897	0.72%
16	SUIBIAN TRADING PTY LTD	2,404,397	0.68%
17	CS FOURTH NOMINEES PTY LIMITED <hsbc 11="" a="" au="" c<="" cust="" ltd="" nom="" td=""><td>2,113,343</td><td>0.60%</td></hsbc>	2,113,343	0.60%
18	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED <nt-comnwlth a="" c<="" corp="" super="" td=""><td>1,952,947</td><td>0.55%</td></nt-comnwlth>	1,952,947	0.55%
19	JUST GROUP INVESTMENT PTY LTD <just a="" c<="" group="" investment="" td=""><td>1,934,559</td><td>0.55%</td></just>	1,934,559	0.55%
20	ARMADA TRADING PTY LTD	1,610,064	0.46%
	Totals: Top 20 holders of ordinary fully paid shares	276,064,449	78.39%
	Total remaining holders balance	76,088,093	21.61%

# ASX Additional Information (cont.)

#### 3. Substantial shareholders

The following information is current at July 25, 2022 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	46,584,812
Bakers Brothers Life Sciences LP	28,763,289
USB Group AG and its related bodies corporate	23,795,053
Bank of America Corporation and its related bodies corporate	20,914,194

## 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

Michael Sistenich

Non-Executive Director

Lawrence Gozlan

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

#### PRINCIPAL ADMINISTRATIVE OFFICE

Level 4, 650 Chapel Street South Yarra, Victoria 3141

www.opthea.com

Telephone: +61 (3) 9826 0399

#### **BANKERS**

Commonwealth Bank of Australia Melbourne, Victoria

#### **AUDITORS**

Deloitte Touche Tohmatsu Tower 2, Brookfield Place 123 Georges Terrace Perth, Western Australia 6000

#### **SOLICITORS**

Gilbert and Tobin 101 Collins Street Melbourne, Victoria 3000

### **SHARE REGISTER**

Computershare Investor Services Pty Ltd Yarra Falls, 452 Johnston Street Abbotsford, Victoria 3067

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

#### STOCK EXCHANGE LISTING

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

Opthea Limited ADS options are quoted on the US Securities and Exchange Commission (SEC) NASDAQ (code: OPT).

