

## Appendix 4E Preliminary Final Report

OPTHEA LIMITED ABN 32 006 340 567

### YEAR ENDED JUNE 30, 2021 RESULTS FOR ANNOUNCEMENT TO THE MARKET

)	June 30, 2021 \$	June 30, 2020 \$	Movement %
Results			
Revenues from ordinary activities	440,615	539,514	down 18.3%
Loss from ordinary activities after tax attributable to members	(45,344,496)	(11,123,199)	Loss has increased 307.7%
Loss for the year attributable to members	(45,344,496)	(11,123,199)	Loss has increased 307.7%
NTA Backing			
Net tangible asset backing per ordinary security	0.39	0.17	

#### **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.

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ANNUAL REPORT 2020 - 2021 Se only

# 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 U.S. Nasdaq exchange in 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 ageing 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.

# Contents

5

6

8

2020-2021 HIGHLIGHTS STATISTICS AND NUMBERS PIPELINE TO COMMERCIALIZATION CHAIRMAN'S REPORT **CEO'S REPORT** 10 **DIRECTORS' REPORT** 29 MANAGEMENT TEAM 32 FINANCIAL REPORT IBC CORPORATE INFORMATION

## 2020–2021 Highlights

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Aug 21, 2020	Opthea successfully completed End-of-Phase 2 meetings with the U.S. Food and Drug Administration (FDA), and a Scientific Advice meeting with the European Medicines Agency (EMA), to obtain guidance on the Phase 3 clinical development plans of OPT-302 as a treatment for wet AMD.
Aug 24, 2020	Opthea announced plans to conduct a registered public offering and U.S. listing on the Nasdaq exchange.
Sep 10, 2020	Opthea appointed the Company's first US-based director to its Board. Mr Daniel Spiegelman was appointed Non-Executive Director and Chair of the of the Audit and Risk Committee.
Oct 12, 2020	Opthea appointed Dr Jeremy Levin as Chairman of the Board.
Oct 16, 2020	Opthea's American Depositary Shares (ADSs) began trading on the Nasdaq Global Select Market under the symbol "OPT."
Oct 21, 2020	Opthea closed its US\$128.2 million Initial Public Offering (IPO) in the U.S.
Oct 27, 2020	Opthea received A\$8.5m R&D tax incentive from the Australian Taxation Office for research and development costs incurred in the 2019/2020 financial year.
Feb 17, 2021	Opthea presented at the 10th Annual SVB Leerink Global Healthcare Conference and provided corporate update.
Mar 15, 2021	Opthea treated the first patient in the Phase 3 pivotal program of OPT-302 in patients with treatment-naïve wet AMD. The first patient was enrolled by Dr Allen Hu in Maryland, U.S.A.
Mar 17, 2021	Opthea presented at the Oppenheimer 31st Annual Healthcare Conference and provided a corporate update.
Mar 31, 2021	Opthea received an initial Pediatric Study Plan (iPSP) waiver from the U.S. FDA for OPT-302. The Company will not have to conduct an additional study in the pediatric population for use in the U.S.
Jun 1, 2021	Dr Julia Haller and Ms Judith Robertson were appointed Non-Executive Directors, expanding the Board's strengths in clinical and commercialization strategy.
Jul 6, 2021	The U.S. FDA granted Fast Track designation for OPT-302 in combination with anti-VEGF-A therapy for the treatment of patients with wet AMD. The Fast Track Designation offers benefits to expedite the OPT-302 Phase 3 clinical program and potential approval process.
Aug 9, 2021	ShORe and COAST Phase 3 clinical trials opened recruitment to patients in Canada.

#### Did you know

Wet (neovascular) age-related macular degeneration is the leading cause of vision loss in people over the age of 50.

#### Did you know

OPT-302, administered by injection into the eye, inhibits VEGF-C and VEGF-D to further block the growth and leakage of abnormal retinal blood vessels implicated in mediating treatment resistance to anti-VEGF-A therapies.

2

## Statistics and Numbers

\_ raised in Opthea's IPO on Nasdaq exchange

<u>JS\$128M</u>

# US\$11.9BN

2019 worldwide sales revenue for Lucentis<sup>®</sup> and Eylea<sup>®</sup> in retinal diseases

3.5 million people in the U.S. and Europe have wet AMD 9900 patients to be enrolled

into each of Opthea's Phase 3 trials, ShORe and COAST +14.2

letters mean change in visual acuity from baseline to week 24 in Phase 2b patients receiving OPT-302 combination therapy

+5.7

letters additional vision gain in Phase 2b at week 24 in patients with occult and minimally classic wet AMD lesions treated with OPT-302 combination therapy compared to ranibizumab alone >80%

approximate proportion of wet AMD patients with occult and minimally classic lesions 2H CY 2023 expected reporting date for

Phase 3

Zero

therapies targeting novel mechanisms approved for wet AMD over past decade 2034

year OPT-302 Composition of Matter patents extend to, with further data and market exclusivity periods possible >45%

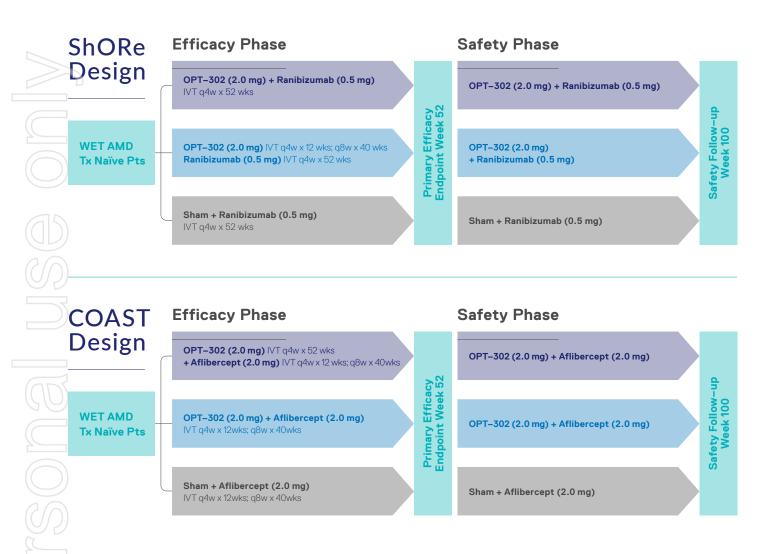
proportion of wet AMD patients who do not experience significant vision gains following regular ongoing treatment with standard of care therapies

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### Did you know

Standard of care therapies do not block VEGF-C and VEGF-D, which may explain why many patients fail to respond fully or maintain vision despite receiving anti-VEGF-A therapy.

## Pipeline to Commercialization



Opthea is conducting two concurrent global, multi-center, double-masked, sham-controlled Phase 3 trials known as ShORe (Study of OPT-302 in combination with Ranibizumab) and COAST (Combination OPT-302 with Aflibercept Study).

Both ShORe and COAST are being conducted in patients with wet AMD who have not received prior therapy (treatment naïve patients) and will enroll ~990 patients each. ShORe will assess the efficacy and safety of intravitreal 2.0 mg OPT-302 in combination with 0.5 mg ranibizumab (Lucentis). COAST will assess the efficacy and safety of intravitreal 2.0 mg OPT-302 in combination with 2.0 mg aflibercept (Eylea).

The primary endpoint of the studies is the mean change in Best Corrected Visual Acuity

from baseline to week 52 for OPT-302 combination therapy compared to anti-VEGF-A monotherapy. Each patient will also continue to be treated for a further year to evaluate extended safety and tolerability over a two-year period.

A number of secondary endpoints will also be evaluated, including effects of OPT-302 combination therapy on other key measures of visual function, as well as anatomical changes of wet AMD lesions assessed by optical coherence tomography (OCT) and fluorescein angiography (FA) imaging. In addition, extended durability of the OPT-302 treatment effect on clinical outcomes with less frequent every eight-weekly dosing will be compared with OPT-302 administered on an every four-weekly dosing regimen, in combination with each VEGF-A inhibitor.

#### Did you know

Lucentis<sup>®</sup> (ranibizumab) and Eylea<sup>®</sup> (aflibercept) are standard of care medicines administered by injection into the eye to block VEGF-A.

## Chairman's Report

"Despite the unparalleled circumstance that our nation, our industry, and our company face, Opthea has advanced significantly. Our focus as a company has been to recapitalize, advance our clinical trials, create better visibility for our company within the global markets, and build our board and management. The work to accomplish these goals continues."

#### Dear Shareholders

The last year in the history of Opthea has been a year of tremendous change set against the backdrop of a global pandemic. The board and management of Opthea send our best wishes to shareholders in the hope that they and their loved ones have passed this last year without major mishap. We also express the wish that with the technological achievements of vaccines that the global dislocation and tragedy around us will progressively diminish.

Despite the unparalleled circumstance that our nation, our industry, and our company face, Opthea has advanced significantly. Our focus as a company has been to recapitalize, advance our clinical trials, create better visibility for our company within the global markets, and build our board and management. The work to accomplish these goals continues. It is notable that in the last year we have greatly strengthened the Board of Directors with the addition of Judith and Julia, we have initiated Phase 3 trials, and we were listed on NASDAQ. At this stage we are now focused on building and strengthening the management team and advancing our clinical trials, while bringing to the attention of investors around the world the remarkable potential that we believe our product OPT-302 holds.

Over the last year while attention has been focused by investors on novel technologies and long-acting versions of much older medicines, there has been no fundamental shift in the treatment paradigm for macular degeneration; consequently the market potential for OPT-302 remains great. This excites us. We are motivated to deliver the value that we believe is inherent in our product and our approach. We plan to execute and to the best of our ability deliver that attention to our programs.

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

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Jeremy Levin D.Phil., MB BChir

### Did you know

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Women have a higher risk of developing wet AMD than men.

4



#### Did you know

Wet AMD impacts quality of life and affects the ability to read, recognize faces, drive or watch TV.

## CEO's Report

"Our forging of a new path is therefore driven by several factors, most notably the need to improve outcomes for patients with retinal eye diseases"



#### Dear Shareholders

At Opthea, we recognize that in seeking to improve vision and address the unmet medical need that remains for wet AMD patients despite the availability of VEGF-A inhibitors, we are forging a new but important path for wet AMD therapies.

There is no doubt that VEGF-A targeted therapies have revolutionized the treatment of wet AMD and whilst many patients experience stabilization or improvement in visual acuity, a majority of patients fail to achieve 20/40 or better vision after 12 months of treatment. In addition, many experience insufficient gains in visual acuity limiting the ability to resume routine daily activities such as driving and reading following regular treatment with standard of care treatments. We also recognize that the disease biology is complex and not driven by a single molecule or pathway. Thus, for these reasons amongst others, we see and believe in the potential of the novel mechanism of OPT-302, by blocking VEGF-C and VEGF-D, to address limitations in the efficacy of current treatments for wet AMD and other retinal diseases.

Our forging of a new path is therefore driven by several factors, most notably the need to improve outcomes for patients with retinal eye diseases; that there have been no new therapies targeting novel mechanisms approved for wet AMD since the approval of the first VEGF-A inhibitor for wet AMD over 15 years ago; that the sound scientific rationale for targeting VEGF-C and VEGF-D is supported by our Phase 2b trial outcomes demonstrating superior vision gains in patients receiving combination OPT-302 therapy; and that there are few agents in development targeting novel pathways that may address shortfalls in efficacy with standard of care treatments.

From a commercial perspective, our approach is differentiated from other investigational agents as OPT-302 is complementary when used in combination with the class of VEGF-A targeted therapies that account for an expanding market opportunity of >US\$12BN per annum.

Operationally, I am pleased to report that irrespective of the significant challenges presented by the worldwide COVID-19 pandemic to the biopharmaceutical industry over the past 12 months, Opthea has continued to successfully advance its two large Phase 3 pivotal registrational clinical trials for OPT-302 in wet AMD.

Building on successful End-of-Phase 2 and Scientific Advice regulatory meetings with the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) respectively, we finalized the Phase 3 development pathway for OPT-302 which included manufacturing and the design of clinical study protocols for two global, multi-center, randomized, sham-controlled Phase 3 clinical trials, ShORe and COAST. Our decision to investigate OPT-302 in combination with two approved standard of care VEGF-A inhibitors, ranibizumab (Lucentis®) in the ShORe trial and aflibercept (Eylea®) in the COAST trial, favorably positions OPT-302 for future broad use with VEGF-A targeted therapies in general including currently approved treatments, as well as next generation treatments that may be approved in the future. This approach is inherent in the Company's strategy to conduct a registrational Phase 3 clinical trial program that maximizes the commercial potential of OPT-302 to offer improved visual acuity outcomes to patients with wet AMD.

From a regulatory perspective, we have also achieved additional important and significant regulatory milestones over the past 6 months. Firstly, the significant unmet medical need in the management of wet AMD and the potential role that OPT-302 may have in addressing it, was acknowledged by the FDA in July 2021 with Fast Track designation granted for OPT-302 in combination with anti-VEGF-A therapy. This designation helps to speed clinical development, regulatory review, and market entry upon approval of treatments with a potential to address serious conditions, with the aim of getting important new therapies to patients more quickly. The benefits of Fast Track designation include more frequent meetings and communications with the FDA as well as a Rolling Review of completed sections of its Biologic Drug Application (BLA) which will expedite the Phase 3 development program and subsequent approval review process. Furthermore, an initial Pediatric Study Plan (iPSP) waiver was also received from the FDA in March 2021, which means that Opthea will not have to conduct an additional study of OPT-302 in a pediatric population for use in the U.S.

The achievement of these milestones and the regulatory guidance from the FDA and EMA has provided Opthea with clear direction, and we believe there is a well-defined regulatory pathway in place to advance OPT-302 through Phase 3 registrational trials in the treatment of wet AMD in support of future filings for global marketing approval and commercial launch including the U.S. and Europe.

During the year, concurrent with the Company's interactions with the FDA and EMA, Opthea undertook an extensive process to prepare for the initiation of the Phase 3 ShORe and COAST trials, including identification of global clinical trial sites and investigators to participate and recruit patients. In addition, we successfully manufactured several large-scale batches of OPT-302 at cGMP quality for use in the ShORe and COAST trials and in support of future commercial efforts.

Our Phase 3 program is truly a global one. Over an approximate 18-month period, both trials will each enroll approximately 990 patients from more than 20 countries worldwide. A key focus of our current activities is to continue our interactions with regulatory authorities worldwide to facilitate completion of all site activations on a country-by-country basis. As a culmination of these efforts, in March 2021, we achieved a key milestone for the company with the announcement that the first patients had been treated in our Phase 3 pivotal program. Since then we have continued to recruit patients in the U.S. and prepare for enrollment in other countries around the world. In August 2021, recruitment opened to patients in Canada and we are on-track to have sites actively recruiting patients in Europe and Asia Pacific

With this strong foundation and recognizing the scope of Phase 3 and commercialization activities, Opthea has worked to further establish the Company as a globally recognized, emerging player in ophthalmology. To that end, Opthea completed a U.S. initial public offering (IPO) and NASDAQ listing in October 2020, raising US\$128.2 million (AU\$164.9 million) equity capital. The proceeds will primarily be used to progress OPT-302 in pivotal Phase 3 registration trials.

Aligned with our U.S. growth strategy, we were delighted to welcome Dr Jeremy Levin as Chairman of the Board in October 2020. Dr Levin, currently Chairman and CEO of Ovid Therapeutics (NASDAQ: OVID), is an experienced biotechnology and pharmaceutical company director and executive having lead Teva Pharmaceutical Industries (TLV: TEVA) as President and CEO and has held various senior executive roles at Bristol-Myers Squibb (NYSE: BMY) executives to build out our U.S. team will position the Company for success and increased shareholder value.

Looking ahead, a key focus for Opthea over the next 12 months is to continue the execution of the Phase 3 pivotal program for OPT-302 in wet AMD. To date, and thankfully, despite a challenging external environment, Opthea's dedicated team have progressed the development of OPT-302 with minimal impact from the COVID-19 pandemic. As our Phase 3 programs advances, we will continue to proactively assess the pandemic's impact on a country-by-country basis and manage our operations accordingly.

Finally, I wish to sincerely and personally thank Mr Geoffrey Kempler, who, as part of a planned succession plan, retired as Chairman of Opthea in October 2020. Mr Kempler was appointed Chairman in 2015 and his tenure included the company's

" As we move closer to our objective of reporting Phase 3 topline data in 2H CY 2023, we will continue to closely monitor patient enrollment and compliance to ensure successful execution of the pivotal registrational program."

lover the following months. As we move closer to our objective of reporting Phase 3 topline data in 2H CY 2023, we will continue to closely monitor patient enrollment and compliance to ensure successful execution of the pivotal registrational program.

I am enormously proud of the achievements over the past several years of Opthea's dedicated and experienced Australian based team. Most notably they drove the execution of the Company's Phase 2b clinical trial in wet AMD which successfully reported superior vision outcomes in treatment naïve patients who received OPT-302 combination therapy. This significant, proof-of-concept data demonstrated the potential of VEGF-C/D inhibition with OPT-302 to improve vision outcomes in patients over and above standard of care anti-VEGF-A monotherapy and set us on to late-stage Phase 3 clinical development and preparation for commercialization. and Novartis (SWX: NOVN). Dr Levin brings a wealth of strategic and industry experience to the Board that is critical for positioning Opthea for growth and commercialization in the near-term.

The Board further expanded its strengths in clinical and commercialization strategy with the appointments of Dr. Julia Haller and Ms. Judith Robertson as independent non-executive directors. Dr Haller is an internationally recognized ophthalmologist and vitreoretinal surgeon, currently serving as Ophthalmologist-in-Chief at Wills Eye Hospital in Philadelphia. Ms Robertson is an accomplished life sciences commercial executive with an extensive track record for building commercial organizations and launching multiple ophthalmic products. We have no doubt that the expanded board of internationally recognized leaders, together with the imminent recruitment of senior

transition to late-stage clinical development and recognition of the inherent potential of OPT-302 to improve vision outcomes in patients with retinal eye disease.

Further, I thank all of our employees, shareholders, investigators and patients for their ongoing support throughout the 2021 financial year. I look forward to updating shareholders as we progress towards our goals and work to achieve our strategic and operational objectives.

Megan Baldwin, PhD CEO & Managing Director Opthea Limited

## Directors' Report

The board of directors of Opthea Limited submits its report for the year ended June 30, 2021 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 (appointed October 5, 2020)

Megan Baldwin, Managing Director and Chief Executive Officer

Geoffrey Kempler, Non-Executive Director and Chairman (resigned October 12, 2020)

Michael Sistenich, Non-Executive Director

Lawrence Gozlan, Non-Executive Director (appointed July 24, 2020)

Daniel Spiegelman, Non-Executive Director (appointed September 10, 2020)

Julia Haller, Non-Executive Director (appointed June 1, 2021)

Judith Robertson, Non-Executive Director (appointed June 1, 2021)

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

D.Phil., 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 D.Phil. in Chromatin Structure, all from University of Oxford, and a MB BChir from the University of Cambridge.

#### MEGAN BALDWIN

PhD, MAICD 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 and audit committees. Michael Sistenich has advised a wide range of global institutions, high net worth individuals and companies on healthcare investments over the past 20 years. He is a healthcare specialist in international investment management and investment banking, and led the Bell Potter team which advised the Company through the \$17.4 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. 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. 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.

## JUDITH ROBERTSON B.A., MBA

### Non-Executive Director

Judith Robertson was appointed non-executive director of Opthea in June 2021. Ms. Robertson was most recently Chief Commercial Officer of Eleusis Ltd. and serves on the board of Durect Corporation, a Nasdaq listed company developing therapies for acute organ injury and chronic liver diseases. She was previously Chief Commercial Officer of Aerie Pharmaceuticals where she oversaw the launch of Rhopressa®, the first product in 20 years to target a new mechanism of action for the treatment of glaucoma, and the launch of the combination product Rocklatan<sup>®</sup>, 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 B.A. with honors from Ryerson University, Canada. She also holds an MBA from Northwestern University, Kellogg School of Management.

### 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	Since 1997
	(NASDAQ)	
2	Lundbeck (ASX)	Since 2017
Megan Baldwin	Invex Therapeutics (ASX)	Since 2020
Lawrence Gozlan	Alterity Therapeutics Limited	Since 2011
7	(ASX)	
Daniel Spiegelman	Myriad Genetics (NASDAQ)	Since 2020
	Jiya Acquisition Corp	Since 2020
	(NASDAQ)	
	Spruce BioScience	Since 2020
	(NASDAQ)	
Judith Robertson	Durect (NASDAQ)	Since 2019
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 granted under LTIP and NED Plans
Megan Baldwin	3,839,398	3,000,000
Jeremy Levin	_	3,000,000
Geoffrey Kempler	900,960	1,500,000
Michael Sistenich	520,178	1,500,000
Lawrence Gozlan	1,877,357	2,000,000
Daniel Spiegelman	-	2,000,000

### SHARE OPTIONS

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

Grant date	Expiry date	Granted to	Exercise price	Number of options granted
March 7, 2016	March 7, 2021	Directors under the LTIP and NED plan	\$036	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
				25,969,000

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 2020-21 included planning and initiation of its Phase 3 program in wet AMD, including the conduct of meetings with the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA), finalization of the design and clinical protocols for two Phase 3 pivotal trials, manufacturing of OPT-302 for use in the Phase 3 clinical trials and the initiation of patient recruitment at multiple sites in the U.S. In addition, Opthea conducted activities to support Phase 3 clinical site activations in Europe, Asia-Pacific and Latin America.

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:

- <sup>7</sup> The major expenditure of the Group has been in relation to R&D, in particular costs associated with the Phase 2b and Phase1b/2a clinical trials of OPT-302 for wet AMD and DME and the initiation of the Phase 3 clinical trials;
- Total R&D expenditure amounted to US\$25,891,851 (2020: US\$12,064,007) . 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\$11,403,170 (2020: US\$13,108,968);
- Opthea received an R&D tax incentive payment during the year of US\$5,834,100, (2020: US\$10,118,697); and

/ The consolidated net loss of the Group for the year was US\$45,344,496 after an income tax benefit of US\$4,938,846 (2020: loss of US\$11,123,199 after an income tax benefit of US\$5,708,766).

#### **Financial Position**

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

- / Consolidated cash balances as at June 30, 2021 amounted to US\$118,193,177 (2020: US\$42,650,858);
- / Receivables of US\$5,538,184 (2020: US\$6,063,725) include the Opthea Group's expected refund of R&D tax incentives for the year to June 2021 of US\$4,972,898 (2020: US\$5,868,152);
- / The Group has a net current asset surplus of US\$135,011,031 (2020: US\$44,285,716); and
- / The net tangible asset backing per share as at June 30, 2021 was US\$0.39 (2020: US\$0.17); Opthea's share price was A\$1.34 (2020: A\$2.36).

#### 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.

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<sup>®</sup>) and aflibercept (Eylea<sup>®</sup>), approved for the treatment of wet AMD, together generated worldwide revenues in excess of US\$11.9 billion in 2019. 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 intra-vitreal 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 planning and initiation of its Phase 3 pivotal program in wet AMD, including engagement with regulatory agencies globally and manufacture of OPT-302 to cGMP standards for use in the clinical trials.

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.

#### **Regulatory Engagement**

In August 2020, Opthea successfully completed End-of-Phase 2 meetings with the U.S. Food and Drug Administration (FDA), and a Scientific Advice meeting with the European Medicines Agency (EMA). The regulatory engagement provided Opthea with guidance on our Phase 3 clinical program for OPT-302 in wet AMD and associated manufacturing processes that we believe will support the submission of a Biologics License Application in the U.S. and Marketing Authorization Application in Europe.

Further regulatory milestones were achieved during the year, firstly with our successful application to the FDA for an initial Pediatric Study Plan (iPSP) waiver, which was received in March 2021. The receipt of the waiver means that Opthea will not have to conduct an additional study of OPT-302 in the pediatric population for the use of OPT-302 in this U.S. population. Furthermore, in July 2021, the FDA granted Fast Track designation for OPT-302 in combination with anti-VEGF-A therapy for the treatment of patients with wet AMD. We believe the FDAs Fast Track designation acknowledges the significant unmet medical need in the management of wet AMD, and the potential role that OPT-302 may have in addressing it. The FDA's Fast Track Designation for OPT-302 offers benefits to expedite the Phase 3 clinical program and subsequent potential approval process, Including more frequent communication and meetings with the FDA, and a Rolling Review of completed sections of its BLA.

Following the agreement by the FDA and EMA on key aspects of the proposed Phase 3 clinical trial designs, the design of two concurrent, global, multi-center, randomized, sham-controlled trials evaluating OPT-302 in combination with either ranibizumab (the ShORe trial) or aflibercept (the COAST trial), were finalized.

#### 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).
- COAST: Combination OPT-302 with Aflibercept Study (Study OPT-302-1005).

ShORe and COAST will enroll treatment-naïve patients.

In ShORe, treatment-naïve patients with wet AMD will be 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 will be 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 trial 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 these 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.

In March 2021, the first patients were treated in our Phase 3 pivotal program, and since that time, we have continued to activate additional clinical trial sites and recruit patients in the U.S. In August 2021, the first sites opened enrollment in Canada and we are on-track to initiate patient recruitment in Europe and Asia Pacific over the following months. In total, we expect to enroll approximately 990 patients into each trial, with patients recruited from more than 20 countries worldwide, and to report top-line data in the second half of calendar year 2023.

#### Corporate Update

Aligned with Opthea's strategy to build the profile of the company globally, and to more effectively access the U.S. capital markets, the Company completed a U.S. initial public offering (IPO) and NASDAQ listing in October 2020. The IPO raised US\$128.2 million (A\$164.9 million) with participation from Australian, US and UK investors. Opthea is now dual-listed on the ASX on NASDAQ where its American Depositary Shares (ADS) are listed at a ratio of 8 ordinary shares to one ADS.

Opthea is also working to broaden Opthea's geographical reach by expanding its operations and building a US-based team of senior executives. In addition, over the past 12 months, the Company expanded its Board of Directors, which included welcoming Dr Jeremy Levin as Chairman. Dr Levin is an experienced biotechnology and pharmaceutical company director and executive. He is currently Chairman and Chief Executive Officer of Ovid Therapeutics and serves on the board of Lundbeck (OMX: LUN). Prior to founding Ovid, Dr Levin was President and CEO of Teva Pharmaceutical Industries Ltd (TLV: TEVA) and before Teva, held senior executive positions at Bristol-Myers Squibb (NYSE: BMY) and Novartis (SWX: NOVN).

In addition, in June 2021, Dr Julia Haller and Ms Judith Robertson joined the Board as independent Non-Executive Directors, expanding the Board's strength in clinical and commercialization strategy. Dr. Haller is an internationally recognized ophthalmologist and vitreoretinal surgeon, currently serving as Ophthalmologist-in-Chief and William Tasman, MD Endowed Chair at Wills Eye Hospital in Philadelphia. Ms. Robertson is an accomplished life sciences

commercial executive with an extensive track record for building, leading and launching several commercial organizations and products including successfully launching multiple ophthalmic products for pharmaceutical and biotechnology companies.

#### Intellectual property

Opthea owns a patent family covering the OPT-302 molecule, and uses thereof, extending out to February 2034. This patent has been filed in 19 jurisdictions and has already granted in the United States, Europe (validated in 38 countries), Japan, Australia, New Zealand, Malaysia, Singapore, Mexico, South Africa, Colombia and Russia. The patent application has been accepted for grant in Canada and Israel, and is currently pending in China, Brazil, India, South Korea, Indonesia and the Philippines.

The United States patent, which granted in August 2017, includes broad claims to the OPT 302 molecule, and analogues thereof and their use to treat disorders involving neovascularization, including eye diseases such as wet AMD and DME.

In the United States, Opthea has another granted patent relating to soluble VEGFR 3 molecules which includes composition of matter claims to soluble VEGFR 3 molecules (such as OPT 302) and extends out to November 2026.

### 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.

## MPACT 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. Although operations to date have not been materially negatively affected by the COVID-19 pandemic, at this time 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.

## FUTURE DEVELOPMENTS

Opthea continues to advance the clinical development of OPT-302 to key clinical and commercial milestones by progressing manufacturing, regulatory engagement, and Phase 3 pivotal trials in wet AMD.

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

#### Wet AMD:

- Continue GMP manufacturing activities of OPT-302 for Phase 3 clinical trials and in support of future commercial efforts;
- Progress development of a co-formulation of OPT-302 with a biosimilar VEGF-A inhibitor; and
- Publish outcomes of the Phase 2b wet AMD trial in a peer reviewed journal.

#### Corporate:

- Broaden Opthea's geographical reach by establishing U.S. based operations;
- / Ensure the global investment and pharmaceutical/ biotechnology community is aware of the commercial potential inherent in OPT-302;
- / Continue to pursue expanded clinical and business development opportunities, including the potential investigation of OP-302 in other retinal indications; and
- / Prepare for various and all opportunities to advance further development of OPT-302 through investment out-reach and engagement with pharmaceutical/biotechnology companies in the sector.

### SIGNIFICANT EVENTS AFTER BALANCE DATE

There are no other significant events after June 30, 2021 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, 2021. Under the Company's Directors' and Officers' Liabilities Insurance Policy, the Company shall not release to any third party or otherwise publish details of the nature of the liabilities insured by the policy or the amount of the premium. Accordingly, the Company relies on section 300(9) of the *Corporations Act 2001* to exempt it from the requirement to disclose the nature of the liability insured against and the premium amount of the relevant policy.

## DIRECTORS' MEETINGS

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

		Directors'	Meetings of committees				
		meetings	Audit & Risk	Nomination	Remuneration		
Ν	umber of meetings held:	6	5	2	5		
N	umber of meetings attended:						
	Geoffrey Kempler (resigned October 12, 2020)	1	1	_	1		
2	Jeremy Levin (appointed October 5, 2020)	5	4	2	5		
	Michael Sistenich	6	5	2	5		
ノ	Lawrence Gozlan (appointed July 24, 2020)	6	5	2	5		
	Daniel Spiegelman (appointed September 10, 2020)	5	5	2	5		
	Julia Haller (appointed June 1, 2021)	1	1	1	1		
	Judith Robertson (appointed June 1, 2021)	1	1	1	1		
	Megan Baldwin	6	5	2	5		
$\sim -$	Megan Balawin	0	0	2	0		

#### 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	Daniel Spiegelman (ceased June 24, 2021)		
Lawrence Gozlan (ceased June 24, 2021)	Daniel Spiegelman	Lawrence Gozlan		
Judith Robertson (June 24, 2021)	-	Julia Haller (June 24, 2021)		

## 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 27 and forms part of the directors' report for the financial year ended June 30, 2021.

## 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, 2021. 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
Geoffrey Kempler (resigned October 12, 2020)	Chairman, Non-executive director
Julia Haller (appointed June 1, 2021)	Non-executive director
Judith Robertson (appointed June 1, 2021)	Non-executive director
Daniel Spiegelman (appointed September 10, 2020)	Non-executive director
Michael Sistenich	Non-executive director
Lawrence Gozlan (appointed July 24, 2020)	Non-executive director

Executive officers	
Megan Baldwin	Chief Executive Officer and Managing Director
Karen Adams	Vice President Finance
(appointed June 15, 2021)	and Company Secretary
Mike Tonroe	Chief Financial Officer
(resigned June 24, 2021)	and Company Secretary

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, 2021, 43% of the directors and 63% 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 2021 or 2020.

#### 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 2021 financial year in August 2021. Based on the achievement of operational objectives in the financial year, the remuneration committee has determined there will be US\$244,145 STI bonus paid to KMP for the 2021 financial year (2020: US\$112,247). 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 \$A. Refer to Note 3 Change in presentation and functional currencies for more information in regard to the determination of the change.

	2021 US\$	2020 US\$	2019 A\$	2018 A\$	2017 A\$
Revenue including finance income	440,615	539,514	914,840	1,143,822	573,421
Loss before tax	(50,283,342)	(16,831,966)	(35,547,034)	(28,919,488)	(9,360,808)
Tax benefit	4,938,846	5,708,767	14,636,973	12,017,248	3,167,912
Loss after tax	(45,344,496)	(11,123,199)	(20,910,061)	(16,902,240)	(6,192,896)

2021 and 2020 is US\$ with remaining years presented in A\$ refer to Note 3 Change in presentation and functional currencies.

	2021 US\$	2020 US\$	2019 A\$	2018 A\$	2017 A\$
Basic loss per share	(0.14)	(0.04)	(0.09)	(0.04)	(0.04)
Net Tangible Asset (NTA) backing per share @ June 30	0.39	0.17	0.12	0.19	0.27
Opthea share price @ June 30	A\$1.34	A\$2.36	0.67	0.53	0.75

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 A\$453,200 per annum from July 1, 2020.

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 remunerationplus 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 contract at any time without notice if serious misconduct has occurred. Where termination with cause occurs, the executive is only entitled to that portion of remuneration that is fixed and only up to the date of termination.

#### Non-executive directors

The base non-executive director fee is US\$75,000 per annum for the Chairman, US\$50,000 per annum for other US based non-executive directors, and A\$67,500 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/A\$13,140, and general committee fees of US\$5,000/A\$6,570 per annum.

Non-executive directors are not provided with retirement benefits 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	Term- ination benefits	Share- based payment		Tota
)		Salary & Fees US\$	Cash bonus¹ US\$	Super- annuation US\$	Long Service Leave US\$	Term- ination Pay US\$	Options US\$	Total US\$	perform- ance related %
Non-Executive di	irectors	5:							
Jeremy Levin⁵	2021	54,032	_	_	_	-	1,158,465	1,212,497	96%
)	2020	_	_	_	_	_	-	_	-
Geoffrey Kempler <sup>6</sup>	2021	21,534	-	2,046	-	_	-	23,580	0%
-	2020	60,683	-	5,765	-	_	85,228	151,676	56%
Michael Sistenich	2021	64,344	_	_	_	_	-	64,344	0%
	2020	40,274	_	3,826	-	_	85,228	129,328	66%
Lawrence Gozlan <sup>2</sup>	2021	60,416	_	_	_	-	1,252,173	1,312,589	95%
-	2020	_	_	_	_	_	_	_	-
 Daniel Spiegelman⁴	2021	64,583	_	_	_	_	1,487,000	1,551,583	96%
	2020	_	_	_	_	_	_	_	-
Julia Haller <sup>3</sup>	2021	4,250	_	_	_	_	_	4,250	0%
-	2020	_	_	_	_	_	_	_	-
Judith Robertson <sup>3</sup>	2021	4,250	_	_	_	_	_	4,250	0%
	2020	_	_	_	-	_	_	_	-
Sub-total									
Non-executive	2021	273,409	_	2,046	_	_	3,897,638	4,173,093	93%
directors	2020	100,957	_	9,591	_	_	170,456	281,004	619
Executive directo	ors:								
Megan Baldwin	2021	338,618	147,166	45,666	_	_	_	531,450	289
	2020	295,346	67,988	34,517	_	_	170,458	568,309	429
Other Key Manag	ement	Personnel:							
Karen Adams <sup>7</sup>	2021	31,039	_	2,949	_	_	_	33.988	0%
	2020	_	_	_	_	_	_	_	
Mike Tonroe <sup>8</sup>	2021	237,535	71,314	28,889	_	_	_	337,738	219
	2020	172,404	44,259	20,524	_	_	79,837	317,024	39%
Totals	2021	880,601	214,480	79,550	-	-	3,897,638	5,076,269	81%
	2020	568,707	112,247	64,632	_	_	420,751	1,166,337	46%

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

2 Lawrence Gozlan was appointed as a non-executive director on July 24, 2020. Mr Gozlan's annual director fee is A\$67,500.

3 Director appointed June 1, 2021.

4 Director appointed September 10, 2020.

5 Director appointed October 5, 2020

6 Director resigned October 12, 2020

7 Appointed June 15, 2021

8 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 read details of options that vested during the reporting period are as follows:

	During the financial year			
Name	Number of options granted	Number of options vested <sup>1</sup>		
Jeremy Levin	3,000,000	750,000		
Daniel Spiegelman	2,000,000	500,000		
Lawrence Gozlan	2,000,000	500,000		
Mike Tonroe	-	600,000		

 $\mathbb T$  Options that vested during the financial year were originally granted in the year ended June 30, 2021 and June 30, 2019.

Options Granted during the year have the following Fair values at Grant date, US\$0.88, US\$1.24 and US\$1.05 with the following exercise price US\$1.56, US\$2.16 and US\$3.24, for Jeremy Levin, Daniel Spiegelman and Lawrence Gozlan, 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.

#### Exercise of options granted as compensation

During the reporting period, 5,845,804 shares were issued to KMP on the exercise of 8,400,000 of options previously granted as compensation.

During the year, 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 A\$1.672 for 7,000,000 options and A\$1.647 for 1,400,000 options and an exercise price of A\$0.48 for 7,800,000 options and A\$0.855 for 600,000 options.

	No. of options	No. of ordinary shares of Opthea		Amount	Expiry date
Name	exercised	Limited issued	Issue date	unpaid	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		or		Financial years in which	Vesting
	of options	Grant date	% vested	% forfeited <sup>1</sup>	grant vests	Conditions
Megan Baldwin	1,320,000	March 7, 2016	100%	0%	July 1, 2015	Continued
	1,320,000	March 7, 2016	100%	0%	July 1, 2016	service
	1,360,000	March 7, 2016	100%	0%	July 1, 2017	
$\bigcirc$	3,000,000	November 29, 2018	100%	0%	July 1, 2019	
Jeremy Levin	750,000	January 19, 2021	25%	0%	July 1, 2020	Continued
75	750,000	January 19, 2021	0%	0%	July 1, 2021	service
	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
	330,000	March 7, 2016	100%	0%	July 1, 2016	service
	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
	500,000	October 12, 2020	0%	0%	July 1, 2021	service
	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
	500,000	October 12, 2020	0%	0%	July 1, 2021	service
	500,000	October 12, 2020	0%	0%	July 1, 2022	-
	500,000	October 12, 2020	0%	0%	July 1, 2023	

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

#### Options over equity instruments

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

Number of options:		Held at July 1	Granted as compen- sation	Options exercised	Lapsed	Forfeited	Held at June 30	Vested during the year	Vested and exercisable
Megan Baldwin	2021	7,000,000	-	(4,000,000)	_	_	3,000,000	_	3,000,000
	2020	7,000,000	-	_	_	_	7,000,000	3,000,000	7,000,000
Jeremy Levin	2021	-	3,000,000	_	_	-	3,000,000	750,000	750,000
	2020	_	-	_	-	-	-	-	_
Geoffrey Kempler <sup>1</sup>	2021	3,500,000	-	(2,000,000)	-	_	1,500,000	-	1,500,000
	2020	3,500,000	-	_	-	-	3,500,000	1,500,000	3,500,000
Daniel Spiegelman	2021	_	2,000,000	_	_	_	2,000,000	500,000	500,000
	2020	_	-	_	-	_	-	_	_
Lawrence Gozlan	2021	_	2,000,000	_	_	_	2,000,000	500,000	500,000
	2020	-	-	_	_	_	-	-	_
Michael Sistenich	2021	2,500,000	-	(1,000,000)	_	_	1,500,000	_	1,500,000
	2020	2,500,000	-	_	-	_	2,500,000	1,500,000	2,500,000
Other executives									
Mike Tonroe <sup>2</sup>	2021	1,400,000	-	(1,400,000)	_	_	_	_	_
	2020	1,400,000	-	_	-	-	1,400,000	600,000	1,400,000
Total	2021	14,400,000	7,000,000	(8,400,000)	_	_	13,000,000	1,750,000	6,250,000
99	2020	14,400,000	-	-	-	-	14,400,000	6,600,000	14,400,000

1. Geoffrey Kempler resigned October 12, 2020.

🗌 🖄 Mike Tonroe resigned as at June 24, 2021. All options had been converted prior to his resignation.

## **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 directors							
Jeremy Levin	2021	-	_	_	-	-	_
	2020	_	_	-	-	-	_
Geoffrey Kempler <sup>1</sup>	2021	900,960	_	1,425,837	-	_	2,326,797
	2020	900,960	_	_	_	_	900,960
Michael Sistenich	2021	520,178	_	712,919	_	_	1,233,097
	2020	520,178	_	_	_	_	520,178
Daniel Spiegelman	2021	_	_	_	_	_	_
	2020	_	_	_	_	_	_
Lawrence Gozlan	2021	_	_	_	1,877,357	_	1,877,357
	2020	_	_	_	_	_	_
Julia Haller	2021	_	_	-	-	_	_
	2020	_	_	_	-	_	-
Judy Robertson	2021	_	_	_	-	_	-
	2020	_	_	_	-	_	-
Executives							
Megan Baldwin	2021	987,723	_	2,851,675	_	_	3,839,398
	2020	987.723	_	_	_	_	987,723
Karen Adams	2021	_	_	_	_	_	_
)]	2020	_	_	_	_	_	-
Mike Tonroe <sup>1</sup>	2021	_	_	855,373	-	(855,373)	-
<u>}</u>	2020	_	—	_		_	-
Total	2021	2,408,861	-	5,845,804	1,877,357	(855,373)	9,276,649
	2020	2,408,861	-	-	-	-	2,408,861

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, 2021.

For and on behalf of the board:

(\_

Megan Baldwin CEO & Managing Director Opthea Limited

Melbourne August 30, 2021

## Declaration of Independence

**Deloitte.** 

Deloitte Touche Tohmatsu ABN 74 490 121 060

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

30 August 2021

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 2021, I declare that to the best of my knowledge and belief, there have been no contraventions of:

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

Yours faithfully

.

DELOITTE TOMME TOMMATSU DELOITTE TOUCHE TOMMATSU

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.

"Our Phase 3 program is truly a global one. Over an approximate 18-month period, both trials will each enroll approximately 990 patients from more than 20 countries worldwide. A key focus of our current activities is to continue our interactions with regulatory authorities worldwide to facilitate completion of all site activations on a country-by-country basis."

MEGAN BALDWIN PHD, MAICD

## Management Team



## 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.

## RICHARD CHADWICK PHD

### Head of Intellectual Property

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

## Management Team (Cont.)



## MIKE GEROMETTA PHD Head of CMC Development

Mike Gerometta has been Head of Chemistry, Manufacturing & Controls (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.

## IAN LEITCH PHD Director – Clinical Research

lan Leitch has been Director of Clinical Research of Opthea since September 2011. He has over 20 years of research and management experience from drug discovery through clinical development in biotechnology/pharmaceutical companies.

For the five years prior to joining Opthea, he was a member of the Medical Sciences group at Amgen Inc in Thousand Oaks, California, involved in the development of novel therapeutics in Amgen's oncology pipeline. In his role as Senior Manager in the Early Development Oncology Therapeutic Area, he had responsibility for the oversight, design, management and execution of Phase 1 – 2 clinical studies in oncology.

Prior to joining Amgen, he spent eight years at Miravant Medical Technologies in Santa Barbara, California. He held positions of increasing responsibility, including Senior Program Manager for Cardiovascular Research and Clinical Study Director for Ophthalmology. At Miravant, he managed preclinical efficacy studies, developed relationships with Key Opinion Leaders and designed Phase 1 – 2 clinical studies in a collaboration with the cardiovascular device company Guidant Inc.

He previously held the position of NHMRC Senior Research Officer at the University of Newcastle and was based at the John Hunter Hospital in Australia. He received his BSc (Hons), PhD from the Department of Pharmacology, Faculty of Medicine, at Monash University and completed part of the doctoral studies at the University of California, Santa Barbara.

## CLARE PRICE BPHARM Director of Clinical Development

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

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





### CONTENTS

- **33** CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME
- **34** CONSOLIDATED STATEMENT OF FINANCIAL POSITION
- **35** CONSOLIDATED STATEMENT OF CHANGES IN EQUITY
- **36** CONSOLIDATED STATEMENT OF CASH FLOWS
- **37** NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
- 70 DIRECTORS' DECLARATION
- 71 INDEPENDENT AUDITOR'S REPORT
- 76 ASX ADDITIONAL INFORMATION

# Consolidated Statement of Profit or Loss and Other Comprehensive Income

FOR THE YEAR ENDED JUNE 30, 2021

	Note	2021 US\$	Restated 2020 US\$
Revenue	7	68,613	59,061
Other income	8	398,951	522,082
Research and development expenses	9	(25,891,851)	(12,064,008)
Patent expenses		(137,666)	(282,042)
Intellectual property costs		(291,235)	(74,938)
Administrative expenses	10	(13,399,748)	(4,702,860)
Occupancy expenses	10	(18,445)	(23,272)
Net foreign exchange gain/(loss)	11	(11,011,961)	(265,989)
)			
Loss before income tax		(50,283,342)	(16,831,966)
Income tax benefit	12	4,938,846	5,708,767
Loss for the year		(45,344,496)	(11,123,199)
Other comprehensive income			
Items that will not be reclassified subsequently to profit or loss:		100 707	
Fair value gains on investments in financial assets		469,767	41,098
Other comprehensive income for the period, net of tax		469,767	41,098
Total comprehensive loss for the year		(44,874,729)	(11,082,101)
Loss for the year is attributable to:			
Owners of the Company	24	(45,344,496)	(11,123,199)
		(45,344,496)	(11,123,199)
Total comprehensive loss for the year is attributable to:			
Owners of the Company		(44,874,729)	(11,082,101)
2		(44,874,729)	(11,082,101)
Loss per share attributable to the owners of the Company:			
<ul> <li>Basic and diluted loss per share (cents)</li> </ul>	13	(14.15)	(4.27)

The above consolidated statement of profit or loss and other comprehensive income should be read in conjunction with the accompanying notes. All amounts presented in respect of prior periods have been restated to reflect the change in presentation currency as set out in the accounting policies.

# Consolidated Statement of Financial Position

# AT JUNE 30, 2021

	Note	2021 US\$	Restated 2020 US\$	Restated 2019 US\$
Assets	Note	00φ	004	000
Current assets				
Cash and cash equivalents	14	118,193,177	42,650,858	15,121,820
Current tax receivable	12	4,972,898	5,868,152	10,278,082
Receivables	15	565,286	195,573	207,701
Prepayments	16	14,386,155	329,151	298,156
Total current assets		138,117,516	49,043,734	25,905,759
Non-current assets				
Investments in financial assets	17	_	199,417	501,454
Plant and equipment		23,259	25,568	37,963
Right-of-use asset	18	93,852	167,460	_
Prepayments	19	174,541	_	_
Total non-current assets		291,652	392,445	539,417
Total assets		138,409,168	49,436,179	26,445,176
Liabilities				
Current liabilities				
Payables	20	2,501,518	4,053,961	4,179,453
Lease liabilities	18	112,965	99,745	-
Other financial liabilities		-	163,548	17,971
Provisions	21	492,002	440,765	378,168
Total current liabilities		3,106,485	4,758,019	4,575,592
75				
Non-current liabilities				
Lease liabilities	18	-	82,545	-
Provisions	22	16,915	27,643	17,445
Total non-current liabilities		16,915	110,188	17,445
Total liabilities		3,123,400	4,868,207	4,593,037
Net assets		135,285,768	44,567,972	21,852,139
Equity				
Contributed equity	23	234,147,526	113,852,364	80,331,016
Pre-funded warrants	23	-	_	_
Accumulated losses	24	(124,123,982)	(78,779,486)	(67,656,287)
Reserves	24	25,262,224	9,495,094	9,177,410
Total equity		135,285,768	44,567,972	21,852,139

The above consolidated statement of financial position should be read in conjunction with the accompanying notes. All amounts presented in respect of prior periods have been restated to reflect the change in presentation currency as set out in the accounting policies.

# Consolidated Statement of Changes in Equity

FOR THE YEAR ENDED JUNE 30, 2021

	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, 2019 (Restated)		80,331,016	_	2,401,769	517,700	6,257,941	(67,656,287)	21,852,139
Fair value gains on investments in financial assets*	24	_	_	_	41,098	_	_	41,098
Loss for the year*		_	_	_	_	_	(11,123,199)	(11,123,199)
Total comprehensive income and expense for the period		_	-	-	41,098	_	(11,123,199)	(11,082,101)
Recognition of share-based payment	24	_	_	732,688	_	_	_	732,688
Issue of ordinary shares on the exercise of options	23	284,828	_	(284,828)	_	_	_	_
lssue of ordinary shares	23	33,236,520	_	_	_	_	_	33,236,520
Exchange on conversion	24	-	-	266,451	(7,389)	(430,336)	-	(171,274)
Balance at June 30, 2020 (Restated)		113,852,364		3,116,080	551,409	5,827,605	(78,779,486)	44,567,972
As at July 1, 2020 (Restated)		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*	24	_	_	_	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	24	_	_	3,897,638	_	_	_	3,897,638
Issue of ordinary shares on the exercise of options	23	3,271,542	-	(3,271,542)	-	-	_	-
Issue of ordinary shares and pre-funded warrants, net of issuance cost \$10,126,959	23	105,477,591	11,546,029	-	-	_	_	117,023,620
Issue of ordinary shares on exercise of pre-funded warrants net of issuance costs \$1,099,412	23	11,546,029	(11,546,029)	_	_	_	_	_
Exchange on conversion	24	_	_	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

\* Amounts are after tax.

The above consolidated statement of changes in equity should be read in conjunction with the accompanying notes. All amounts presented in respect of prior periods have been restated to reflect the change in presentation currency as set out in the accounting policies.

# Consolidated Statement of Cash Flows

FOR THE YEAR ENDED JUNE 30, 2021

Note	2021 US\$	Restated 2020 US\$
Cash flows from operating activities		
Interest received	390,128	496,159
Royalty and license income received	103,031	96,189
Grant income	26,949	41,629
Payment of lease interest	(5,782)	(5,147)
Payments to suppliers, employees and for research & development and intellectual property costs (inclusive of GST)	(51,894,593)	(16,437,147)
Research and development tax incentive scheme credit received	5,834,100	10,118,697
Net cash flows used in operating activities 27	(45,546,167)	(5,689,620)
Cash flows from investing activities		
Cash received on disposal of financial asset 17	669,184	335,746
Purchase of plant and equipment	(12,702)	(2,531)
Net cash flows provided by investing activities	656,482	333,215
Cash flows from financing activities		
Rayment of lease liabilities	(87,373)	(66,781)
Net proceeds on issue of shares	105,477,591	32,951,692
Net proceeds on issuance of pre-funded warrants	11,546,029	_
Cash received for ordinary shares issued on exercise of options	_	284,828
Net cash flows provided by financing activities	116,936,247	33,169,739
Net increase/(decrease) in cash and cash equivalents	72,046,562	27,813,334
Effects of exchange rate changes on the balance of cash held in foreign currencies	3,495,757	(284,296)
Cash and cash equivalents at beginning of year	42,650,858	15,121,820
Cash and cash equivalents at the end of the year 14	118,193,177	42,650,858

The above consolidated statement of cash flows should be read in conjunction with the accompanying notes. All amounts presented in respect of prior periods have been restated to reflect the change in presentation currency as set out in the accounting policies.

# 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, 2021.

# 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.

# Change in presentation and functional currencies

# Functional currency

An entity's functional currency is the currency of the primary economic environment in which the entity operates. During the current year the Group's operations have continued to move further towards being US\$ denominated and several other factors during the period have also contributed to the Group changing its functional currency during the year, such as the completion of U.S. initial public offering (IPO) and the NASDAQ listing in October 2020, opening a US subsidiary in May 2021 for a planned expansion into the US, and expanding the Board of Directors with the appointment of four 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 U.S. capital market and all of the Group's budgeting and planning is conducted solely in dollars led to the Directors determining that U.S. 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 (A\$) to U.S. dollar (US\$) effective January 1, 2021.

The change in functional currency has been applied prospectively with effect from January 1, 2021 in accordance with the requirements of the Accounting Standards. To give effect in functional currency, the assets and liabilities of the Group were converted into U.S. dollars at a fixed exchange rate of US\$1:A\$1.2973.

# Presentation Currency

Following the change in functional currency, the Group changed its presentation currency from Australian dollars (A\$) to US\$. The change in presentation currency to better reflect the Group's business activities and to enhance access to U.S. 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 is accounted for retrospectively, including the restatement of 2019 Balance Sheet. In making this change in presentation currency, the Group followed the requirements set out in AASB 121 The Effects of Changes in Foreign Exchange Rates. As required by AASB 121, the consolidated statement of profit and loss and other comprehensive income and the consolidated statement of cash flows for each period have been translated into the presentation currency using the average exchange rates prevailing during each reporting period. All assets and liabilities have been translated using the exchange rates prevailing at the consolidated statement of financial position dates. Shareholders' equity transactions have been translated using the rates of exchange in effect as of the dates of various capital transactions. All resulting exchange differences arising from the translation are included as a separate component of other comprehensive income. All comparative financial information has been 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\$14.5 million at January 1, 2021.

# 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\$). The prior year financial information has been restated to United States dollars, and any financial information related to earlier financial periods remains presented in Australian Dollars (A\$) unless otherwise indicated.

# ii. Transactions and balances

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

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

# Financial assets and liabilities

Recognition and derecognition of financial assets

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

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

# Cash and cash equivalents

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

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

# Other receivables

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

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

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

# Investments

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

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

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

# SUMMARY OF ACCOUNTING POLICIES (CONT.)

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.

# Other financial liabilities

Other financial liabilities in the Consolidated Statement of Financial Position represent the year end marked-to-market value of forward rate foreign exchange contracts to purchase US dollars (Contracts) which were entered into prior to the change in functional currency which took place on January 1, 2021. These Contracts were used to settle US dollar denominated payables and expired within one year.

The foreign exchange loss on recognition of the Contracts was included in 'net foreign exchange gain/(loss)' in the Consolidated Statement of Profit or Loss and Other Comprehensive Income.

# 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.

#### Leases

The Group assesses at contract inception whether a contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

The Group applies a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. The Group recognizes lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

#### Right-of-use assets

Right-of-use assets are recognized at the commencement date of the lease (that is the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and any impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Right-of-use assets are depreciated on a straight-line basis over the shorter of the lease terms and the estimated useful lives of the assets.

#### Lease liabilities

Lease liabilities are recognized at the commencement date of the lease at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable.

In calculating the present value of lease payments, the Group uses its incremental borrowing rate at the lease commencement date because the interest rate implicit in the lease is not readily determinable. The incremental borrowing rate is determined using market yields on bonds with similar terms to maturity. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in lease payments (e.g., a change to future lease payments resulting from a change in an index or rate).

# SUMMARY OF ACCOUNTING POLICIES (CONT.)

#### Leases of low-value assets

For short-term leases (lease term of 12 months or less) and leases of low-value assets (such as photo copiers and telephones), the Group has opted to recognize a lease expense on a straight-line basis as permitted by IFRS 16. This expense is presented within "administrative expenses" in the Consolidated Statement of Profit or Loss and Other Comprehensive Income.

# 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, 2021 and 2020, 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.

# 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.

# SUMMARY OF ACCOUNTING POLICIES (CONT.)

During the years ended June 30, 2021 and 2020, the Group's only revenue related to sales-based royalties.

#### Income tax

#### Current tax

Current tax assets and liabilities for the current and prior periods are measured at the amount expected to be recovered from or paid to the taxation authorities based on the current period's taxable income.

The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted by the reporting date.

#### Research and development tax incentive

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

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

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

# Deferred tax

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

Deferred income tax liabilities are recognized for all taxable temporary differences except when the deferred income tax liability arises from the initial recognition of goodwill or of an asset or liability in a transaction that is not a business combination and that, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss.

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.

# SUMMARY OF ACCOUNTING POLICIES (CONT.)

#### 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.

# Comparatives

The comparative period has been restated due to the change in presentation currency.

# 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, 2020 and 2021, Opthea progressed Phase 2b wet age-related macular degeneration (wet AMD) and Phase 1b/2a diabetic macular edema (DME) 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, 2021 and 2020.

#### 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 future 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, 2021 and 2020, the Group has recognized an R&D tax incentive receivable of \$5 million and \$6 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, 2021 and 2020 is based on the legislation as currently enacted as at June 30, 2021 and 2020, respectively. Any proposed changes to the legislation, such as rate changes to the eligibility requirements, may have a retrospective impact if the legislation is passed, currently no such legislative 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

# A CRITICAL ACCOUNTING JUDGMENTS AND KEY SOURCES OF ESTIMATION UNCERTAINTY (CONT.)

done by either analogizing with AASB 112 or with AASB 120. In the Group's opinion, the R&D tax incentive should be presented by analogizing to AASB 112 because the nature of the incentive is considered to be more closely aligned to income taxes, based on the following considerations:

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

The ATO, which is the tax authority in Australia, manages the annual claims process as the R&D tax incentive is included in the Group's annual income tax return.

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

#### 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 and presentation currency changed from Australian dollars to U.S. dollars as disclosed in Note 3.

The Group's assets, liabilities and equity which were previously denominated in Australian dollars were translated into U.S. 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 31. 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 2018-7 Amendments to Australian Accounting Standards

   Definition of Material;
- AASB 2019-1 Amendments to Australian Accounting Standards
   References to the Conceptual Framework; and

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

In the current year, the Group has applied a number of amendments to Australian Accounting Standards and Interpretations issued by the Australian Accounting Standards Board (AASB) that are effective for an annual period that begins on or after July 1, 2020. Their adoption has not had any material impact on the disclosures or on the amounts reported in these financial statements.

# 5. APPLICATION OF NEW AND REVISED ACCOUNTING STANDARDS (CONT.)

#### 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 2021-5 Amendments to Australian Accounting Standards – Deferred Tax related to Assets and Liabilities arising from a Single Transaction	January 1, 2023
AASB 2021-2 Amendments to Australian Accounting Standards – Disclosure of Accounting Policies and Definition of Accounting Estimates.	January 1, 2023
AASB 2015-10 Amendments to Australian Accounting Standards – Effective Date of Amendments to AASB 10 and AASB 128 and AASB 2017-5 Amendments to Australian Accounting Standards – Effective Date of Amendments to AASB 10 and AASB 128 and Editorial Corrections	January 1, 2022 (Editorial corrections in AASB 2017-5 apply from January 1, 2018)
AASB 2020-1 Amendments to Australian Accounting Standards – Classification of Liabilities as Current or Non-Current	January 1, 2023
AASB 2020-6 Amendments to Australian Accounting Standards – Classification of Liabilities as Current or Non-Current – Deferral of Effective date	January 1, 2023
AASB 2020-3 Amendments to Australian Accounting Standards – Annual Improvements 2018-2021 and Other Amendments	January 1, 2023
AASB 2021-3 Amendments to Australian Accounting Standards – COVID-19-Related Rent Concessions	June 1, 2021
In addition, at the date of outboringtion of the financial statements the following IACD Stands	uda au di IEDO lata wa wata ti awa

In addition, at the date of authorization of the financial statements the following IASB Standards and IFRS Interpretations Committee Interpretations were on issue but not yet effective, but for which Australian equivalent Standards and Interpretations have not yet been issued:

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.

1

#### SEGMENT INFORMATION 6.

The Group operates in one industry and one geographical area, those being the biotechnology and healthcare industry and Australia (as the U.S subsidiary was only incorporated in May 2021 and currently has no transactions or contracts with customers), 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 financial year 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 \$68,613 (2020: \$59,061) was generated from customers based outside Australia. The Group does not have any major customers. All property, plant and equipment are located in Australia.

# 7. REVENUE

	2021 US\$	Restated 2020 US\$
Sales based royalties	68,613	59,061
Total revenue	68,613	59,061

# OTHER INCOME

	2021 US\$	2020 US\$
Sales based royalties	68,613	59,061
Total revenue	68,613	59,061
8. OTHER INCOME	2021 US\$	Restated 2020 US\$
Finance income	372,001	480,453
Grant income	26,950	41,629
Total other income	398,951	522,082
9. RESEARCH AND DEVELOPMENT EXPENSES		

# RESEARCH AND DEVELOPMENT EXPENSES

	2021 US\$	Restated 2020 US\$
Research project costs <sup>1</sup>	25,891,851	12,064,008
Total research and development expenses	25,891,851	12,064,008

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

10. EXPENSES

$\overline{\mathbf{D}}$	2021 US\$	Restated 2020 US\$
(a) Administrative expenses		
Employee benefits expenses:		
Salaries and fees	1,794,840	1,424,237
Cash bonuses	479,501	193,588
Superannuation	188,543	141,019
Share-based payments expense	3,897,638	732,688
Total employee benefits expense	6,360,522	2,491,532
Other expenses:		
Insurance	4,419,433	335,786
Investor relations costs	285,071	254,212
Audit and accounting	647,549	221,410
Travel expenses	1,459	44,521
Payroll tax	18,766	134,845
Legal fees	83,605	372,431
Advisory fees	393,843	416,082
Consultancy costs	367,070	_
Other expenses	714,328	334,262
Total other expenses	6,931,124	2,113,549
Depreciation of:		
Equipment and furniture	15,012	14,581
Leasehold improvements	_	344
Right-of-use asset	91,656	81,611
Total depreciation expense	106,668	96,536
Loss on disposal of non-current assets	1,434	1,243
<u>}</u>		
Total administrative expenses	13,399,748	4,702,860
(b) Occupancy expenses		
Short term and low value lease expenses	_	1,539
Lease incidental costs	18,445	21,733
Total occupancy expense	18,445	23,272

# 11. NET FOREIGN EXCHANGE (LOSS)/GAIN

	2021 US\$	Restated 2020 US\$
Net foreign exchange (losses)/gains	(11,011,961)	(265,989)
	(11,011,961)	(265,989)

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 where the Company raised US\$128 million, the Company entered into an Australian dollar denominated term deposit worth US\$100 million (A\$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 (A\$) until December 31, 2020, the Group recorded a foreign exchange loss of US\$9m in relation to this transaction.

# 12. INCOME TAX

	2021 US\$	Restated 2020 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	4,938,846	5,708,767
	4,938,846	5,708,767
Deferred tax		
In respect of the current year	-	-
Total income tax benefit recognized in the Statement of Comprehensive Income	4,938,846	5,708,767
(b) Current tax receivable		
Research and Development Tax Incentive Credit receivable	4,972,898	5,868,152

# INCOME TAX (CONT.)

12.

(c) Numerical reconciliation between aggregate income tax benefit recognized in the Statement of Profit of 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:

35	2021 US\$	Restated 2020 US\$
Accounting loss before tax	(50,283,342)	(16,831,966)
At the Company's statutory income tax rate of 30% (2020; 27.5%)	15,085,003	4,628,791
R&D tax incentive on eligible expenses	4,938,846	5,708,767
Non-deductible R&D expenditure	(3,420,951)	(3,624,766)
Other non-deductible expenses – share-based payment expense	(1,169,291)	(201,489)
Amount of temporary differences and carried forward tax losses not recognized	(10,494,761)	(802,536)
Income tax benefit reported in the Statement of Profit or Loss and Other Comprehensive Income	4,938,846	5,708,767
(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:	(2,344,514)	(70.005)
Interest and royalty income receivable (future assessable income)		(70,925)
$\bigcirc$	(2,344,514)	(70,925)
Deferred tax assets related to temporary differences:		
Recognition of tax losses	1,508,764	
Accrued expenses and other liabilities	205,458	303,383
Employee provisions	152,675	128,812
Other miscellaneous items	477,617	430,839
	2,344,514	863,034
Less: temporary differences not recognized	-	(792,109)
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 (2020: \$792,109).

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

The Group had income tax losses of \$20,846,641 and capital losses of \$672,934 at year end (2020: income tax losses of \$14,378,726 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.

# INCOME TAX (CONT.)

(g) Franking credit balance The franking account balance at the of franking credits available for the The franking account balance at the end of the financial year at 30% is A\$227,371 (2020: A\$227,371), which represents the amount of franking credits available for the subsequent financial year and is not recognized in the financial statements.

# 13. EARNINGS PER SHARE

		2021 US\$	Restated 2020 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	(45,344,496)	(11,123,199)
	(b) Weighted average number of shares		
	Weighted average number of ordinary shares on issue for basic earnings per share	320,432,814	260,795,745
	Effect of dilution:		
	Share options	-	_
	Weighted average number of ordinary shares adjusted for the effect of dilution	320,432,814	260,795,745
	Loss per share (basic and diluted in cents)	(14.15)	(4.27)

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.

	plans would generally be included in the calculation due to the conditions of the issuance be position, the options are anti-dilutive and, accordingly, the basic loss per share is the same a		n a loss
	A total number of 16,644,000 options outstanding June 30, 2021 were anti-dilutive and were average number of ordinary shares for the purpose of diluted earnings per share. These opti		
		2021 No.	2020 No.
	NED Plan	10,000,000	6,000,000
<u> </u>	LTIP	6,644,000	12,044,000
		16,644,000	18,044,000
		Annual Report 202	

14. CURRENT ASSETS - CASH AND CASH EQUIVALENTS

$\bigcirc$		2021 US\$	Restated 2020 US\$
Cash	n at bank and in hand	15,538,510	2,077,089
Shor	t-term deposits	102,654,667	40,573,769
Tota	l cash and cash equivalents	118,193,177	42,650,858

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 0.24% (2020: 1.01%).

# 15. CURRENT ASSETS - RECEIVABLES

10	2021 US\$	Restated 2020 US\$
Interest receivable	37,905	56,032
GST receivable <sup>1</sup>	136,239	105,124
Other receivable <sup>1</sup>	391,142	34,417
Total current receivables	565,286	195,573

The GST and other receivables are non-interest bearing. There were no receivables with a material expected credit loss recorded during the financial year (2020: nil).

# 16. CURRENT ASSETS - PREPAYMENTS

	2021 US\$	Restated 2020 US\$
R&D Contract Research Organization	12,551,398	_
Insurance	1,820,059	320,521
Other prepayments	14,698	8,630
Total current prepayments	14,386,155	329,151

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 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 Note 19.

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

	2021 US\$	Restated 2020 US\$
Listed Australian shares – at fair value <sup>1</sup>	-	199,417

					2021 US\$	Restate 202 US
isted Australian shares – at fair value <sup>1</sup>					-	199,4
Details of listed Australian shares .isted investments	Ownership interest	Fair value at June 30²	Exchange on translation	Disposal in the financial year <sup>3</sup>	Fair value gain/(loss) recognized in OCl <sup>4</sup>	Openir fair valu
2021						
Non-current investments:						
Optiscan Imaging Limited		-		(669,184)	469,767	199,4
Total listed investments		-	-	(669,184)	469,767	199,4
Loss of the set to the state of the set of t						
Non-current investments:			(7783)	(335,746)	174,196	169,3
Antisense Therapeutics Ltd Dptiscan Imaging Limited	- 1.73%		(15,852)		(133,098)	348,3
2020 (Restated)			(7,783)	(335,746)	174,196	

During the year ended June 30, 2020, the Group disposed of its remaining investment in ANP for net proceeds of \$335,746. The increase in fair value during the year of \$174,196 was recognized in other comprehensive income. In accordance with the Group's accounting policy, the gain remains within the fair value of investments reserve. The fair value of the investment in ANP at the disposal date was \$335,746. The Group disposed of the investment in line with its Treasury and Investments Policy.

4 A fair value increase of \$469,767 (2020: \$41,098) in the carrying value of investments has been made through other comprehensive income in the year due to a net increase in their market value in the year.

# 18. RIGHT-OF-USE ASSETS

# Right-of-use asset

The Group has a three-year lease contract for its head office premises in Melbourne, Australia which commenced on July 15, 2019. The agreement does not contain any extension options. The carrying amount of the lease at June 30, 2021 and 2020 is as follows:

	2021 US\$	Restated 2020 US\$
Right-of-Use Asset Cost		
Opening balance as at July 1	251,189	_
Additions	-	251,189
Exchange on translation	30,365	-
	281,554	251,189
Right-of-Use Asset Depreciation		
Opening balance as at July 1	(83,729)	-
Charge for the period	(91,656)	(81,611)
Exchange on translation	(12,317)	(2,118)
	(187,702)	(83,729)
Net carrying amount at June 30	93,852	167,460

# Lease liabilities

Lease liabilities are as indicated below.

At the commencement date of the lease of its office premises, the Group recognizes lease liabilities measured at the present value of lease payments to be made over the lease term ending on July 14, 2022, using an incremental borrowing rate of 3%.

15)	2021 US\$	Restated 2020 US\$
Carrying amount at July 1	182,290	_
New lease	-	251,189
Payments	(69,325)	(68,899)
Carrying amount at June 30	112,965	182,290
Maturity analysis:		
Year 1	124,495	105,026
Year 2	-	87,827
9	124,495	192,853
Less: unearned interest	(11,530)	(10,563)
	112,965	182,290
Analyzed into:		
Current portion	112,965	99,745
Non-current portion	-	82,545
	112,965	182,290

# **RIGHT-OF-USE ASSETS** (CONT.)

18. RIGHT-OF-USE ASSETS (CONT.)		
	2021 US\$	Restated 2020 US\$
Amounts recognized in profit or loss:		
Depreciation expense on right-of-use asset	91,656	83,729
Lease finance costs	5,782	5,148
Expense relating to leases of low value assets	7,042	6,497
	104,480	95,374

The Group did not have any short-term leases during the year ended June 30, 2021 and 2020. The above amounts are recorded in Administrative expenses.

# 19. NON-CURRENT ASSETS - PREPAYMENTS

	2021 US\$	Restated 2020 US\$
Insurance	174,541	-
Total non-current prepayments	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.

# 20. CURRENT LIABILITIES - PAYABLES

	2021 US\$	Restated 2020 US\$
Creditors (unsecured) <sup>1</sup>	2,417,719	4,014,818
Pay as You Go (PAYG) tax liability	83,799	39,143
Total current payables	2,501,518	4,053,961

<sup>2</sup>1 Creditors are non-interest bearing and are normally settled on 30 day terms.

# 21. CURRENT LIABILITIES - PROVISIONS

	2021 US\$	Restated 2020 US\$
Annual leave	289,043	277,469
Long service leave	202,959	163,296
Total current provisions	492,002	440,765

# 22. NON-CURRENT LIABILITIES - PROVISIONS

		Restated
	2021	2020
	US\$	US\$
Long service leave 16	6,915	27,643

# 23. CONTRIBUTED EQUITY

	2021 US\$	Restated 2020 US\$
(a) Ordinary shares		
Issued and fully paid at June 30	234,147,526	113,852,364
Movement in ordinary shares:		
Opening balance	113,852,364	80,331,016
Issue of shares in a private placement	-	33,236,520
Issue of shares on exercise of options granted under the LTIP	-	284,828
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	_
Transfer from option reserve	3,271,542	_
	234,147,526	113,852,364
Ordinary shares on issue:	No:	No:
Opening balance	269,157,769	249,414,839
Issue of shares in a private placement	-	18,867,930
Issue of shares on exercise of options granted under the LTIP	5,845,804	875,000
Issue of shares on NASDAQ listing	68,506,400	_
Issue of shares on exercise of pre-funded warrants	7,493,568	_
	351,003,541	269,157,769

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

Issued capital at June 30, 2021 amounted to \$234,147,526 (351,003,541 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, 2021, the company had 6,750,000 Non-Executive Director options remain unexercised with expiry of November 2022 for 1,500,000, October 2023 for 3,000,000 options and January 2024 for 2,250,000 options.

# 23. CONTRIBUTED EQUITY (CONT.)

#### 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 7,000,000 options over ordinary shares under these plans during the year ended June 30, 2021 (note 31). These options had a weighted average fair value at their grant date of \$1.03 per option. During June 30, 2021 8,400,000 options granted under the LTIP and NED Plan were exercised for \$3,271,542. No options were granted under the Plans during the year ended June 30, 2020.

	2021 US\$	Restated 2020 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. 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. During the year 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.

# ACCUMULATED LOSSES AND RESERVES

$\overline{)}$	2021 US\$	Restated 2020 US\$
(a) Movements in accumulated losses were as follows:		
Balance at July 1	(78,779,486)	(67,656,287
Net loss for the period	(45,344,496)	(11,123,199
Balance at June 30	(124,123,982)	(78,779,486
(b) Reserves		
Fair value of investments reserve (i)	1,085,411	551,409
Share-based payments reserve (ii)	4,087,650	3,116,080
Foreign translation reserve (iii)	20,089,163	5,827,605
Total reserves	25,262,224	9,495,094
(i) Movement in fair value of investments reserve:		
Opening balance	551,409	517,700
Fair value gains on investments in financial assets	469,767	41,098
Exchange on translation	64,235	(7,389
Closing balance	1,085,411	551,409
(ii) Movement in share-based payments reserve:		
Opening balance	3,116,080	2,401,769
Share-based payments expense	3,897,638	732,688
Exercise of options	(3,271,542)	(284,828
Exchange on translation	345,474	266,45′
Closing balance	4,087,650	3,116,080
(iii) Movement in Foreign translation reserve:		
Opening balance	5,827,605	6,257,94
Gain/loss on translation	14,261,558	(430,336
Closing balance	20,089,163	5,827,605

#### (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 A\$ to US\$.

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

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

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

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

The board reviews and agrees policies for managing each of these risks as 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 (2020: nil).

The following sensitivity analysis (an annual effect) is based on the interest rate risk exposures at June 30, 2021 and 2020.

At June 30, 2021, 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 impact	
Judgments of reasonably possible movements	2021 US\$	Restated 2020 US\$	
+ 0.50% (50 basis points) (2020: + 0.50%)	359,442	137,676	
0.50% (50 basis points) (2020: – 0.50%)	(359,442)	(137,676)	

The post tax figures include an offset for unrecognized tax losses (bringing the tax effect to nil) for the year ended June 30, 2021 (2020: nil).

Significant assumptions used in the interest rate sensitivity analysis include:

/ The reasonably possible movement of 0.5% was calculated by taking the interest rates as at balance date, moving these by plus and minus 0.5% and then re-calculating the interest on term deposits with the 'new-interest-rate'.

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

#### (ii) Price risk

25.

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

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

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

At June 30, 2021 and 2020, had the share price moved with all other variables held constant, post tax (loss)/profit and equity would have been affected as illustrated in the table below:

	Impact of loss	Impact on equity	Impact of loss	Impact on equity
Judgments of reasonably possible movements	2021 US\$	2021 US\$	Restated 2020 US\$	Restated 2020 US\$
Change in variables				
10% increase in listed share price	_	_	13,450	13,450
10% decrease in listed share price	_	-	(13,450)	(13,450)

#### (iii) Foreign currency risk

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

The Group does not enter into any hedging transactions.

		Consolida		
	AUD	EURO	GBP	CA
2021	2021 US\$	2021 US\$	2021 US\$	202 US
- inancial assets				
Cash	35,646,457	_	_	
Receivables	5,513,541	_	_	
inancial liabilities				
Payables	(1,276,164)	(41,872)	_	(1,29
Other financial liabilities	_	_	_	-
Net exposure	39,883,834	(41,872)	-	(1,29
		Consolida	ated	
	USD	EURO	GBP	CAI
	2020	2020	2020	2020
2020 Restated	US\$	US\$	US\$	US
inancial assets				
Cash	42,417	_	_	
Receivables	25,821	_	_	-
inancial liabilities				
Payables	(3,355,050)	(10,238)	(23,481)	-
Other financial liabilities	(163,547)	-	_	-
	(3,450,359)	(10,238)	(23,481)	

At June 30, 2021 and 2020, had the United States dollar (2020: Australian dollar) moved with all other variables held constant, post tax (loss) profit and equity would have been affected as illustrated in the table below:

		Post tax (loss)/profit impact		
Judgments of reasonably possible movements	2021 US\$	Restated 2020 US\$		
Consolidated				
AUD/USD +10% (2020: +10%)	(2,538,062)	219,569		
AUD/USD –10% (2020: -10%)	3,102,076	(268,361)		

The reasonably possible movements at June 30, 2021 are higher than at June 30, 2020 due mainly to the higher net exposure to the Australian dollar due to significant 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.

# (iv) Credit risk

25.

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

# (v) Liquidity risk

Liquidity risk arises from the financial liabilities of the Group and the Group's subsequent ability to meet their obligations to repay their financial liabilities as and when they fall due. The Group has minimal liquidity risk because of the high balances of cash and cash equivalents; however the Group manages liquidity risk by maintaining adequate reserves and by monitoring forecast and actual cash flows and by matching the maturity profiles of financial assets and liabilities. The financial liabilities of the Group relate to trade payables that are all expected to be paid within 12 months.

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

#### (vi) Fair value

The Group has investments in listed equities which are calculated using the quoted prices in an active market and are considered level 1 fair value measurements. The Group does not have any derivative investments where the fair value is estimated using inputs other than quoted prices that are observable for the asset or liability, either directly (as prices) or indirectly (i.e. derived from prices). The Group also does not hold any financial instruments where fair value measurement uses observable inputs that require significant adjustments based on observable inputs to estimate its value.

Details of the fair value of the investment in financial assets are disclosed in note 17 of the financial statements.

The fair value of financial assets and financial liabilities in the consolidated statement of financial position at June 30, 2021 and 2020 is the same as their carrying amounts.

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

# 26. RELATED PARTY DISCLOSURES

#### (a) Subsidiaries

	Parent en % equity int	
Name of company	2021 %	2020
Vegenics Pty Ltd <sup>1</sup>	100	100
Opthea US Inc <sup>2</sup>	100	-
1 Opthea Limited is the ultimate parent entity. Vegenics Pty Ltd is incorporated in Australia and has the	e same financial vear as Onthea Limite	ed

#### (b) Transactions with related parties

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

# 27. CASH FLOW STATEMENT RECONCILIATION

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

	2021 US\$	Restated 2020 US\$
Cash at bank and in hand (note 14)	118,193,177	42,650,858
75	118,193,177	42,650,858
(b) Reconciliation of net loss after tax to net cash flows from operations		
Net loss for the year	(45,344,496)	(11,123,199)
Adjustments for:		
Income tax benefit recognized in profit or loss	(4,938,846)	(5,708,767)
Depreciation of non-current assets	15,012	14,926
Depreciation of right-of-use asset	91,656	81,611
Share-based payments	3,897,638	732,688
Net exchange differences	11,011,961	265,989
	10,077,421	(4,613,553)
Changes in:		
Payables	(1,552,443)	(125,492)
Receivables	(369,712)	12,127
Prepayments	(14,231,546)	(30,994)
Provisions	40,510	72,794
Net cash flows used in operating activities before tax	(51,380,266)	(15,808,317)
R&D tax incentive received	5,834,099	10,118,697
Net cash flows used in operating activities	(45,546,167)	(5,689,620)
1D	2021 US\$	Restated 2020 US\$
(c) Reconciliation of borrowings arising from financing activities		
Balance at July 1	167,460	_
Non-cash addition <sup>1</sup>		251,189
Payment of lease liabilities	(87,373)	(66,781)
Exchange on translation	13,765	(16,948)
Balance at June 30	93,852	167,460

1 Non-cash addition represents the new lease on the Company's office premises in Melbourne, Australia that commenced on July 15, 2019.

# 28. COMMITMENTS

#### (i) Lease commitments - Group as lessee

Lease commitments are in respect of low value leases which have not been recognized in the Statement of Financial Position. These leases are expensed on a straight-line basis over the term of the lease.

	2021 US\$	Restated 2020 US\$
Within one year	5,304	4,497
After one year but not more than five years	8,398	11,619
	13,702	16,116

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

The Group has entered into research and development contracts and intellectual property license agreements with various third parties in respect of services for the Phase 3 DME clinical trial and the clinical grade manufacture of OPT-302. Expenditure commitments relating to these and intellectual property license agreements are payable as follows:

9 	2021 US\$	Restat 20 U
Within one year	26,377,778	7,660,3
After one year but not more than five years	2,347,060	293,8
After more than five years	_	75,0
	28,724,838	8,029,1
Currently, the biggest Research contract has a 60 day termination clause and a	Il commitments have been limited to a six mont	h commitm
Currently, the biggest Research contract has a 60 day termination clause and a	Il commitments have been limited to a six mont	h commitm
Currently, the biggest Research contract has a 60 day termination clause and a	Il commitments have been limited to a six mont	h commitn

# 29. 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 (2020: \$263,241) and those which could become payable in more than one year total \$11,548,205 (2020: \$11,518,745).

Under these license/collaboration agreements, payments are to be made only if certain research and clinical development milestones rare 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, 2021 in respect of a rental deposit for its office premises of \$43,000 (2020: \$39,391).

# 30. KEY MANAGEMENT PERSONNEL

(a) Compensation of Key Management Personnel

	2021 US\$	Restated 2020 US\$
Short-term employee benefits	1,099,081	680,954
Post-employment benefits	79,550	64,632
Share-based payments expense	3,897,638	420,751
Total compensation	5,076,269	1,166,337

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.

# 31. 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:

	2021 US\$	Restated 2020 US\$
Expense arising from equity-settled share-based payment transactions:		
Director and employee services received	3,897,638	732,688

#### (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.

# SHARE-BASED PAYMENTS (CONT.)

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.

Options/Rights series	Grant date	Grant date fair value US\$	Exercise price US\$	Expiry date	Vesting date
_TIP – director FY2016	March 7, 2016	\$0.14	\$0.36	March 7, 2021	June 30, 201
_TIP – director FY2019	November 29, 2018	\$0.15	\$0.625	November 29, 2022	November 29, 2019
_TIP – employees FY2016	March 31, 2016	\$0.18.	\$0.37	January 1, 2022	January 1, 201
_TIP – employees FY2018	August 23, 2017	\$0.26	\$0.92	January 1, 2023	June 30, 2018
_TIP – employees FY2019	April 3, 2019	\$0.18	\$0.608	April 3, 2023	April 3, 202
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, 202'
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, 202'
NED Plan FY2021	January 19, 2021	\$0.88	\$1.56	January 18, 2025	January 19, 2022
NED Plan FY2021	January 19, 2021	\$0.88	\$1.56	January 18, 2025	January 19, 2023
NED Plan FY2021	January 19, 2021	\$0.88	\$1.56	January 18, 2025	January 19, 2024

# 31. SHARE-BASED PAYMENTS (CONT.)

### (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
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

# (d) Movements in share options during the year

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

	June 30,	2021	June 30,	2020
	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	18,044,000	0.50	18,919,000	0.50
Granted during the year:				
To employees and directors under the LTIP and NED Plan	7,000,000	2.21	_	_
Exercised during the year	(8,400,000)	0.36	(875,000)	0.37
Expired during the year	-	_	_	_
Balance at end of year	16,644,000	1.28	18,044,000	0.50
Exercisable at end of year	11,394,000	0.86	18,044,000	0.50

The share options outstanding at the end of the year had a weighted average exercise price of \$0.86 (2020: \$0.50) and a weighted average remaining contractual life of 628 days (2020: 626 days).

# NET TANGIBLE ASSET BACKING

		Restated
	2021	2020
	US\$	US\$
Net tangible assets (including Right-of-use assets)	0.39	0.17

# 33. AUDITOR'S REMUNERATION

/	2021 A\$	2020 AS
Deloitte and related networks firms:		
Audit or review of the financial report of the entity and any other entity in the consolidated group	408,660	615,00
Statutory assurance services required by legislation to be provided by the auditor	-	
Other assurances and agreed-upon procedures under other legislation or contractual arrangements	45,000	
Other services:		
– Tax compliance services	-	-
- Consulting services	-	-
- Other	-	
	453,660	615,000

#### 35. 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

15)	2021 US\$	Restated 2020 US\$
Current assets	138,331,255	48,912,774
Non-current assets	117,110	392,445
Total assets	138,448,365	49,305,219
Current liabilities	(3,078,269)	(4,653,758)
Non-current liabilities	(16,916)	(110,188)
Total liabilities	(3,095,185)	(4,763,946)
Net assets	135,353,180	44,541,273
Issued capital	234,147,526	113,852,364
Accumulated losses	(124,112,899)	(76,874,382)
Employee equity benefits reserve	4,087,650	3,116,081
Fair value of investments reserve	1,085,411	551,409
Foreign currency translation reserve	20,145,492	3,895,801
Total shareholders' equity	135,353,180	44,541,273
	Year ended June 30, 2021 US\$	Restated Year ended June 30, 2020 US\$
Loss of the parent entity	(45,304,268)	(10,836,631)
Other comprehensive income	469.767	41,098

#### Financial performance

5	Year ended June 30, 2021 US\$	Restated Year ended June 30, 2020 US\$
Loss of the parent entity	(45,304,268)	(10,836,631)
Other comprehensive income	469,767	41,098
Total comprehensive loss of the parent entity	(44,834,501)	(10,795,533)

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

 ${\mathbb T}$ he parent entity does not have any contractual commitments for the acquisition of property, plant and equipment for the year ended June 30, 2021 (2020: nil).

## 5. PARENT ENTITY INFORMATION (CONT.)

### (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 (2020: \$263,241) and those which could become payable in more than one year total \$1,056,099 (2020: \$1,026,640).

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, 2021 in respect of a rental deposit for its office premises of \$43,000 (2020 \$39,391.).

# Directors' Declaration

## FOR THE YEAR ENDED JUNE 30, 2021

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, 2021 and of its performance for the year ended on that date; and
  - (ii) complying with Australian Accounting Standards, *Corporations Regulations 2001*, and International Financial Reporting Standards (IFRS) as disclosed in note 3 of the financial statements; and
- (b) there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

2 This declaration has been made after receiving the declarations required to be made to the directors in accordance with section 295A of the *Corporations Act 2001* for the financial year ended June 30, 2021.

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

Megan Baldwin CEO & Managing Director Opthea Limited

Melbourne August 30, 2021

**Jeremy Levin** Chairman Opthea Limited

# 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

Tel: +61 8 9365 7000 Fax: +61 8 9365 7001 www.deloitte.com.au

# 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 subsidiary (the "Group"), which comprises the Consolidated Statement of Financial Position as at 30 June 2021, the Consolidated Statement of Profit or Loss, the Consolidated Statement of 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 2021 and of its financial performance for the year then ended; and
- (ii) complying with Australian Accounting Standards and the Corporations Regulations 2001.

#### **Basis for Opinion**

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

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

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

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

# Independent Auditor's Report (Cont.)

## **Deloitte.**

#### Key Audit Matters

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

Key Audit Matter	How the scope of our audit responded to the Key Audit Matter
Change in functional and presentation currency from AUD to USD	
Effective 1 January 2021 the Group's functional and presentation currency changed from Australian dollars to U.S. dollars as disclosed in Note 3. The Group's assets, liabilities and equity which were previously denominated in Australian dollars were translated into U.S. dollars on the date the functional currency changed. Significant judgement 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.	<ul> <li>Our procedures included, but were not limited to:         <ul> <li>Obtaining an understanding of how management determined the Group's functional currency.</li> </ul> </li> <li>Assessing the status of significant indicators of functional currency including:         <ul> <li>The currency that mainly influences the Group's capital and operating costs in relation to its ongoing research and development projects</li> <li>The currency in which receipts from equity raising activities are retained.</li> </ul> </li> <li>Challenging management's assessment through inquiry and inspecting documentation to assess whether the date of change in functional currency is reasonable, and</li> <li>Confirming the exchange rates applied and reperforming the translation of underlying balances into U.S. dollars.</li> </ul>
	We also assessed the appropriateness of the disclosures in Note 3 to the financial statements.
Research and development tax incentive	
The Group operates in the biotechnology market and is in the clinical research stage of developing a molecule asset, OPT-302, for treatment of eye diseases. The Group claims Research & Development tax incentives ("R&D tax incentives") provided by the Australian Government as disclosed in Note 4.1.	<ul> <li>Our procedures included, but were not limited to:</li> <li>Assessing the design and implementation of key controls in relation to R&amp;D expenditure and the preparation and review of the R&amp;D tax incentive calculation.</li> <li>Assessing the accounting policy adopted by the Group to account for the R&amp;D tax incentive.</li> </ul>
	In conjunction with our R&D tax specialists we:
For the year ended 30 June 2021, the Group has recognised an R&D tax incentive receivable of \$4.9 million within the consolidated statement of financial position, with a corresponding amount recognised within income tax benefit within the consolidated statement of profit or loss and other comprehensive income.	<ul> <li>Obtained an understanding of the rules and regulations governing R&amp;D tax incentives and the basis used by the Group to recognise the incentive.</li> <li>Assessed the work performed by the Group's external R&amp;D tax advisors to understand the process for the preparation and review of the R&amp;D tax incentive submissions.</li> </ul>

## **Deloitte.**

Key Audit Matter	How the scope of our audit responded to the Key Audit Matter
<ul> <li>Management exercises significant judgement in respect of R&amp;D tax incentives claimed by the Group including: <ul> <li>Determining the accounting policy used in accounting for the R&amp;D tax incentive.</li> <li>Assessing the eligibility of R&amp;D activities and costs attributed to those eligible R&amp;D activities against the rules and regulations governing the R&amp;D tax incentive.</li> <li>Determining the estimated amounts, timing and geographical location of future costs related to the projects for which R&amp;D tax incentive applications have been approved to date.</li> </ul> </li> </ul>	<ul> <li>Assessed management's documentation addressing how the Group's R&amp;D activities satisfy the eligibility criteria outlined in the rules and regulations governing the R&amp;D tax incentives.</li> <li>On a sample basis, inspected R&amp;D expenses to supporting documentation.</li> <li>Tested on a sample basis, management's apportionment of costs to these R&amp;D activities and whether the underlying methodology used for the apportionment is consistent with the rules and regulations governing the R&amp;D tax incentive.</li> <li>Assessed management's R&amp;D project forecasts for eligible activities, including assessing the estimated amounts, timing and geographical location of future costs.</li> </ul>
	We also assessed the appropriateness of the disclosures in Note 2, 4.1 and 12 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 2021, but does not include the financial report and our auditor's report thereon.

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

In connection with our audit of the financial report, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial report or our knowledge obtained in the audit, or otherwise appears to be materially misstated. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

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

The directors of the Company are responsible for the preparation of the financial report that gives a true and fair view in accordance with Australian Accounting Standards and the Corporations Act 2001 and for such internal control as the directors determine is necessary to enable the preparation of the financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

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

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

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

## Independent Auditor's Report (Cont.)

## **Deloitte.**

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.

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 18 to 25 of the Directors' Report for the year ended 30 June 2021.

## **Deloitte.**

In our opinion, the Remuneration Report of Opthea Limited, for the year ended 30 June 2021 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 Tommatsu Deloitre Touche Tommatsu

- Leer

Vincent Snijders Partner Chartered Accountants Perth, 30 August 2021

## 4. DISTRIBUTION OF EQUITY SECURITIES

The number of shareholders, by size of holding, of quoted fully paid ordinary shares as at July 30, 2021 is as follows:

	Fully pa ordinary s	
Category	No. of holders	No. of shares
1,000	3,349	1,835,417
1,001 – 5,000	3,440	9,095,179
5,001 – 10,000	1,055	8,134,870
10,001 – 100,000	971	27,131,374
100,001 and Over	119	304,806,701
Total	8,934	351,003,541
Number of shareholders holding less than a marketable parcel of shares	1,310	318,883

## 2. TWENTY LARGEST SHAREHOLDERS

The names of the 20 largest holders of quoted fully paid ordinary shares and their respective holdings at July 30, 2021 are:

Rank	Name	No. of shares	% interest
1	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	121,305,679	34.56%
2	CITICORP NOMINEES PTY LIMITED	36,818,813	10.49%
3	J P MORGAN NOMINEES AUSTRALIA PTY LIMITED	29,632,302	8.44%
4	UBS NOMINEES PTY LTD	12,105,634	3.45%
15	JAGEN PTY LTD	11,581,484	3.30%
6	CS THIRD NOMINEES PTY LIMITED <hsbc 13a="" au="" c="" cust="" ltd="" nom=""></hsbc>	10,588,622	3.02%
25	BNP PARIBAS NOMS PTY LTD <drp></drp>	10,009,416	2.85%
8	NATIONAL NOMINEES LIMITED	7,969,850	2.27%
9	ARMADA TRADING PTY LIMITED	5,071,967	1.44%
10	MRS MARGARET LYNETTE HARVEY	4,000,000	1.14%
11	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED <gsco a="" c="" customers=""></gsco>	3,156,372	0.90%
12	GAJA HOLDINGS	2,851,675	0.81%
13	LL FAMILY NOMINEES PTY LTD <lani family="" liberman=""></lani>	2,527,897	0.72%
14	SUIBIAN TRADING PTY LTD	2,420,933	0.69%
15	JUST GROUP INVESTMENT PTY LTD <just a="" c="" group="" investment=""></just>	1,934,559	0.55%
16	CS FOURTH NOMINEES PTY LIMITED <hsbc 11="" a="" au="" c="" cust="" ltd="" nom=""></hsbc>	1,823,462	0.52%
17	ARMADA TRADING PTY LTD	1,610,064	0.46%
18	JAGEN PTY LTD	1,439,056	0.41%
19	BNP PARIBAS NOMINEES PTY LTD <agency a="" c="" drpppp="" lending=""></agency>	1,428,898	0.41%
20	GEOFFREY PAUL KEMPLER	1,425,837	0.41%
	Totals: Top 20 holders of ordinary fully paid shares	269,702,520	76.84%
	Total remaining holders balance	81,301,021	23.16%

## 3. SUBSTANTIAL SHAREHOLDERS

The following information is current at July 30, 2021 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	36,253,572
Baker Brothers Life Sciences LP	29,696,496
Bank of America Corporation and its related bodies corporate	17,879,283
UBS Group AG and its related bodies corporate	17,736,308

## . 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).

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# Corporate Information

### 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

Julia Haller Non-Executive Director

Judith Robertson 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** 550 Bourke Street, Melbourne, Victoria 3000

## SOLICITORS

**Gilbert and Tobin** 101 Collins Street, Melbourne, Victoria 3000

### SHARE REGISTER

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

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

### STOCK EXCHANGE LISTING

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

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



opthea.com