

February 23, 2023

# Half-Year Financial Report December 31, 2022

In accordance with Listing Rule 4.2A, we enclose the Half-Year Financial Report (reviewed) on the consolidated results of Opthea Limited ("Opthea", the "Group" or the "Company") for the half year ended December 31, 2022. The previous corresponding periods are the fiscal year ended June 30, 2022 and the half year ended December 31, 2021.

Information in relation to the operational performance, financial performance, cash flows and financial position is included in the attached Appendix 4D Half-Year Financial Report.

This Half-Year Financial Report should be read in conjunction with the Company's Annual Report for the year ended June 30, 2022.

Karen Adams Company Secretary

i

# Appendix 4D

## Half-Year Financial Report

## Opthea Limited ABN 32 006 340 567

REPORTING PERIOD: HALF YEAR ENDED DECEMBER 31, 2022
PREVIOUS CORRESPONDING PERIOD: HALF YEAR ENDED DECEMBER 31, 2021

### **INDEX**

1. Results for announcement to the markets

2 Financial report:

Director's Report
 page 3 of the financial report

Additional Business and Operational Updates page 8 of the financial report

Auditor's Independence Declaration page 10 of the financial report

• Financial Statements pages 11-24 of the financial report

Forward-Looking Statements
 page 25 of the financial report

Directors' Declaration page 26 of the financial report

Independent Auditor's Review Report page 27 of the financial report

This half-year report should be read in conjunction with the Company's 2022 Annual Report and form 20-F FY2022.

Note: The financial figures provided are in United States dollars.

Except with respect to US dollar amounts presented as contractual terms, amounts denominated in US dollars when received or paid and unless otherwise indicated, certain Australian dollar amounts contained in this report have been translated into US dollars at the rate published by the Reserve Bank of Australia as of December 31, 2022. These translations should not be considered representations that any such amounts have been, could have been or could be converted into US dollars or Australian dollars at that or any other exchange rate as of that or any other rate. We have made rounding adjustments to some of the figures included in this report. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that precede.

iii

This report includes trademarks, tradenames and service marks, certain of which belong to the Company and others that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this report appear without the  $^{\circ}$  and  $^{\sim}$  symbols, but the absence of those references is not intended to indicate, in any way, that Opthea will not assert its rights or that the applicable owner will not assert its rights to these trademarks and tradenames to the fullest extent under applicable law. Opthea does not intend its use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

Changes compared to:

# Appendix 4D continued

## Results for announcement to the market

The consolidated results of Opthea Limited for the six months ended December 31, 2022 are as follows:

### REVENUES AND RESULTS FROM ORDINARY ACTIVITIES

		<b>61</b>		
		December 31 2021 %		December 31 2022 US\$
Revenues from ordinary activities	Increased	16%	to	52,107
Loss from ordinary activities before tax	Loss has increased	95%	to	(79,143,755)
Loss from ordinary activities after tax attributable to members	Loss has increased	105%	to	(77,099,014)

An explanation of the figures reported above are contained in the Directors' Report under the heading 'Financial performance.'

### **Shareholder distributions**

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

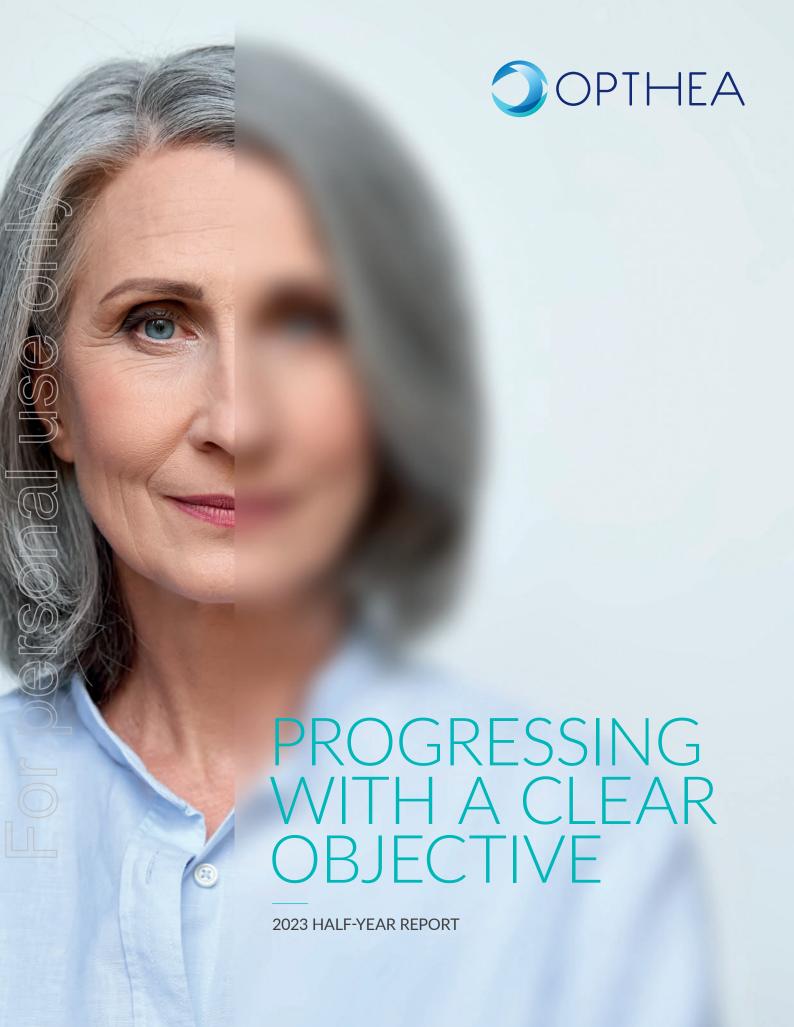
	Consolid	dated
NTA BACKING	December 31 2022 US\$	June 30 2022 US\$
Net tangible asset backing per ordinary security	\$0.18	\$0.20

### Status of review of accounts

The financial report for the half year ended December 31, 2022 has been reviewed. The auditor's review report is included at page 27 of the financial report.



This page has been left blank intentionally.





# Directors' Report

The directors of Opthea Limited submit herewith the financial report of Opthea Limited and its subsidiaries ("Opthea", the "Company" or the "Group") for the half year ended December 31, 2022. In order to comply with the provisions of the *Corporations Act 2001* (Cth), the directors report as follows:

### **Directors**

The names of the Company's Directors in office during the half year and until the date of this report are:

Jeremy Levin	Chairman, Non-Executive Director
Megan Baldwin	Chief Executive Officer and Managing Director
Lawrence Gozlan	Non-Executive Director
Julia Haller	Non-Executive Director
Susan Orr	Non-Executive Director
Quinton Oswald	Non-Executive Director
Michael Sistenich	Non-Executive Director
Dan Spiegelman	Non-Executive Director

## **Operating & Financial Review**

#### FINANCIAL PERFORMANCE

For the half year ended December 31, 2022, the Company's net loss before income tax is US\$79,143,755 (December 31, 2021: US\$40,629,360). The increased loss compared to the prior period was mainly due to the increase in research and development ("R&D") spending, which was attributed to the increase in the number of clinical trial sites and increase in enrollment of patients in the Phase 3 clinical trials of OPT-302 for wet AMD and the continued manufacturing of OPT-302 in support of these trials:

- the total R&D expense was US\$61,433,565 (December 31, 2021: US\$31,819,649);
- the total administrative expenses was US\$14,635,452 (December 31, 2021:US\$5,199,088), this half year incurred higher advisory and legal fees associated with the DFA and equity financing deals approx US\$6.7 million;
- the income tax benefit for the half year is US\$2,044,739 (December 31, 2021: US\$2,916,601); and
- basic earnings per share were a loss of 16.51 cents (December 31, 2021: loss of 10.74 cents).

#### FINANCIAL POSITION

Points to note on the Company's financial position are:

- the cash position at December 31, 2022 was US\$141,772,429 (June 30, 2022: US\$44,631,293);
- a benefit of US\$2,044,739, (December 31, 2021: US\$2,916,601) was recognized in relation to the R&D Tax Incentive in the current period and included in current tax receivable; and
- at December 31, 2022, the Net Tangible Asset backing per share was 18 cents (June 30, 2022: 20 cents).

### **Opthea: Corporate Overview**

Opthea (ASX: OPT; Nasdaq: OPT) is a biopharmaceutical company developing novel therapies to address the unmet need in the treatment of highly prevalent and progressive retinal diseases, including wet age-related macular degeneration ("wet AMD") and diabetic macular edema ("DME"). Opthea's lead product candidate OPT-302 is in pivotal Phase 3 clinical trials and being developed for use in combination with anti-VEGF-A monotherapies to achieve broader inhibition of the vascular endothelial growth factor ("VEGF") family, with the goal of improving overall efficacy and demonstrating superior vision gains over that which can be achieved by inhibiting VEGF-A alone. OPT-302 targets VEGF-C and VEGF-D (together "VEGF-C/D").

# OPTHEA: WORKING TO ADDRESS THE MAJOR UNMET NEED IN WET AMD PATIENTS TO IMPROVE VISUAL FUNCTION OUTCOMES WITH OPT-302 COMBINATION THERAPY OVER AND ABOVE ANTI-VEGF-A MONOTHERAPY

Wet AMD is a progressive, chronic disease of the central retina and the leading cause of visual impairment in the elderly. Progressive vision loss associated with wet AMD contributes to significant healthcare and economic costs globally and greatly impacts ability to perform routine daily activities such as driving and reading.

The hallmark of wet AMD is choroidal neovascularization, which occurs when abnormal blood vessels grow into the retina, beneath 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 retina distortion and fibrous scarring, and often rapid loss of vision.

Wet AMD lesions are historically classified into three lesion types: occult, minimally classic and predominantly classic. Classification is determined by the progression of the abnormal blood vessels into the retina. In occult lesions, blood vessels have not broken through retinal pigment epithelial ("RPE") layer of the eye. Minimally classic lesions have blood vessel growth below and above the RPE. In predominantly classic lesions, a majority of the blood vessels have penetrated the RPE. Lesion classification is important as historically, predominantly classic lesions are highly responsive to anti VEGF-A treatment, whereas minimally classic lesions are moderately responsive and occult lesions are less responsive to VEGF-A inhibitors. Alternatively, minimally classic and occult lesions may be more responsive to therapies targeting VEGF-C and VEGF-D. Opthea believes treatment with OPT-302, a VEGF-C and VEGF-D inhibitor, in combination with approved VEGF-A inhibitors may have the potential to improve visual acuity outcomes in wet AMD patients through broad blockade of VEGF pathways and greater inhibition of abnormal blood vessel growth and fluid leakage in patients with any of these three lesion types.

A member of the VEGF family of proteins, VEGF-A, plays an important role in regulating the growth of abnormal new blood vessels and choroidal neovascularization in wet AMD. Inhibitors of VEGF-A are the standard of care treatments for wet AMD. The leading commercially available VEGF-A inhibitors for the treatment of wet AMD, ranibizumab (Lucentis®) and aflibercept (Eylea®), together with bevacizumab (Avastin®), a VEGF-A inhibitor used off-label, account for approximately 95% of intravitreal injections for wet AMD currently administered worldwide. Recently, rolucizumab (Beovu®) and faricimab (Vabysmo®) have also been approved and launched for wet AMD in addition to biosimilar (generic) versions of ranibizumab (Cimerli® and Byooviz®).

In 2021, Lucentis and Eylea generated combined revenues in excess of US\$12 billion, reflecting the prevalence of retinal disease worldwide and the importance of preserving and improving visual acuity for quality of life.

Although VEGF-A inhibitor therapies improve outcomes for many people with wet AMD, a majority of patients exhibit a suboptimal response to currently available therapies that continues to impact quality of life, with further gains in visual acuity necessary for patients to resume routine daily activities. As such, there remains a very large clinical and market opportunity for novel therapies that address this high unmet medical need for wet AMD patients.

# OPT-302: FIRST AND ONLY NOVEL INVESTIGATIONAL "TRAP" MOLECULE TARGETING VEGF-C AND VEGF-D FOR TREATMENT OF WET AMD

Opthea is investigating a first in-class agent that targets VEGF-C and VEGF-D; additional ligand members of the VEGF family that are mediators of blood vessel growth and vascular leakage and are implicated in the progression of retinal diseases. VEGF-C and VEGF-D function independent of, but in parallel with, VEGF-A to drive these biological processes. In addition, suppression of VEGF-A increases VEGF-C and VEGF-D levels, and may contribute to suboptimal responses to anti-VEGF-A monotherapy.

Opthea is developing OPT-302 as a complementary treatment to be used in conjunction with VEGF-A inhibitors for the treatment of wet AMD and other retinal diseases. By combining administration of OPT-302 with a VEGF-A inhibitor, broader blockade of the VEGF receptor-1, 2 and 3 signalling pathways that contribute to the pathophysiology of retinal diseases, can be achieved, with the potential to further reduce retinal swelling and improve visual acuity in patients. Furthermore, OPT-302 in combination with VEGF-A inhibitors, may result in more durable clinical responses.

The majority of agents currently in clinical development for wet AMD are seeking to reduce the frequency of patient treatments, rather than provide superior vision gain. OPT-302 is a differentiated product in this development landscape, with a key objective to further improve vision outcomes in patients. This approach is complementary to, and not competitive with, the approved class of VEGF-A targeted therapies. By targeting a novel mechanism of action through VEGF-C and VEGF D inhibition, OPT-302 is the most advanced product in clinical development with demonstrated potential to improve patient visual outcomes and tap into an expanding global retina market opportunity of potentially greater than US\$12 billion per annum.

Opthea's Phase 2b clinical data supports the hypothesis that combining OPT-302 with a VEGF-A inhibitor results in more complete and effective inhibition of angiogenesis and vascular leakage in eyes with wet AMD compared to anti-VEGF-A treatment alone. Statistically superior vision gains in patients with treatment-naïve wet AMD were achieved with the intravitreal combination of 2.0 mg OPT-302 and Lucentis (+14.2 letters, p=0.0107), compared with Lucentis monotherapy (+10.8 letters), representing an additional and statistically superior +3.4 letter gain in the total patient population. Furthermore, a mean gain of +5.7 letters (p=0.0002) was observed in patients with minimally classic and occult lesions, lesion types that are typically more difficult to treat with anti-VEGF-A monotherapy and which represented approximately 80% of patients enrolled in the Phase 2b trial. The results of the Phase 2b clinical trial have informed the design and analysis strategy for the pivotal registrational Phase 3 clinical development program, which Opthea believes is optimized for success. Patient recruitment for the Phase 3 clinical trials is ongoing globally.

## Operational update

For the six months ended December 31, 2022, Opthea has made significant progress in obtaining additional funding for the Phase 3 studies and has made strides in the activation of participating trial sites, resulting in increased patient enrollment.

In August 2022, Opthea entered into a Development Funding Agreement ("DFA") with Ocelot SPV LP ("Investor"), an affiliate of Carlyle and Abingworth. Working together with Carlyle and Abingworth's recently formed development company Launch Therapeutics ("Launch Tx"), the Investor agrees to provide funding to Opthea to support its development of OPT-302 for the treatment of wet AMD.

Under the DFA, Investor has committed to provide Opthea US\$120 million in funding which may be increased up to US\$170 million at its option. Through December 31, 2022, US\$85 million of the US\$120 million has been received by Opthea. The remaining tranche of US\$35 million will be paid on or before December 31, 2023, with Investor retaining an option, under certain conditions, to provide an additional US\$50 million in funding. Under the DFA, Opthea is required to use commercially reasonable efforts to develop OPT-302 for the treatment of wet AMD in accordance with the DFA, including pursuant to certain development timelines set forth therein.

Launch Tx has taken on both clinical and commercial risk in funding Opthea, since Opthea will not be required to make any payments to Launch Tx if OPT-302 is not approved for wet AMD in a major territory. In return for the funding provided, Opthea will pay to Investor (1) upon the first to occur of regulatory approval of OPT-302 for the treatment of wet AMD in the US, United Kingdom or European Union ("Regulatory Approval"), fixed payments equal to a total of approximately two times the funding provided, consisting of seven payments, with the first payment due shortly after Regulatory Approval and the remaining six payments payable over a six-year period thereafter, and (2) variable payments equal to 7% of net sales of OPT-302 for the treatment of wet AMD for each calendar quarter. At the time that Investor receives an aggregate of four times the funding provided (US\$680 million if Investor funds the full US\$170 million under the Agreement) (the "Cap"), Opthea's payment obligations under the DFA will be fully discharged. Opthea has the option to discharge its payment obligations to Investor upon Regulatory Approval or a change of control of Opthea by paying an amount equal to the present value of the remaining payments payable to Investor subject to a mid-single-digit discount rate. The DFA not only provides Opthea with significant non-dilutive funding for OPT-302, it also provides access to the clinical and regulatory expertise at Launch Tx. The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by the full text of the DFA, which was filed as an exhibit to Opthea's Annual Report on Form 20-F for the fiscal year ended June 30, 2022.

In connection with the DFA, Opthea also completed a private placement of ordinary shares for aggregate gross proceeds of approximately US\$90 million and a price per ordinary share of A\$1.15 (approximately US\$0.81) (the "equity financing") in September 2022. At December 31, 2022, Opthea had cash and cash equivalents of US\$142 million, which includes the proceeds from the equity financing, together with initial non-dilutive funding under the DFA.

For the six months ended December 31, 2022, the main focus for Opthea was activation of new clinical trial sites worldwide and patient enrollment. With new sites open, and the impact of the COVID-19 pandemic waning, enrollment in our Phase 3 clinical trials continued. The studies are global, multicenter, randomized, sham-controlled, Phase 3 clinical trials referred to as "ShORe: Study of OPT-302 in combination with Ranibizumab" and "COAST: Combination OPT-302 with Aflibercept Study". In each trial, patients are randomized to one of three arms. In the ShORe study patients receive OPT-302 plus Lucentis (on one of two dosing schedules) or Lucentis plus sham injection ("sham"). In the COAST study patients receive OPT-302 plus Eylea (on one of two dosing schedules) or Eylea plus sham. Each trial will enroll approximately 990 treatment naïve patients and will investigate the mean change in best corrected visual acuity from baseline to week 52 for OPT-302 in combination with an approved VEGF-A inhibitor (Lucentis or Eylea) administered on an every 4-week, and on an every 8-week, dosing cycle, compared to treatment

alone with Lucentis in the ShORe trial or Eylea in the COAST trial. The ShORe and COAST Phase 3 trials build upon and maintain these key features of our successful Phase 2b clinical trial of OPT-302 combination therapy for the treatment of wet AMD, while evaluating the administration of OPT-302 in combination with approved VEGF-A inhibitors over a longer treatment period and in a greater number of patients.

As of December 31, 2022, there were over 185 activated clinical trial sites in ShORe in 22 countries. In COAST, there were over 190 clinical trial sites in 30 countries. Typically, each site will only enroll patients in one of the Phase 3 studies.

Over the next twelve months, Opthea will continue to work with our global Clinical Research Organization ("CRO") to increase engagement with trial sites and investigators, and identify eligible patients for enrollment into the ShORe and COAST trials. Enrollment has been challenged in part by the COVID-19 pandemic, supply chain issues, global and regional inflation, national and local recessions, challenges in hiring qualified staff at sites, our CRO and distribution locations, local regulatory approvals, importation and custom requirements and administrative delays. Opthea has undertaken a hiring plan to add a significant number of employees and consultants as Medical Science Liaisons, and clinical operations staff to enhance patient recruitment efforts. Opthea has also undertaken a proactive approach to engage Key Opinion Leaders ("KOL's") and principal investigators at professional meetings and congresses to build awareness of Opthea, OPT-302 and our ShORe and COAST studies. Depending on the enrollment rate and the results of its enrollment activities, subject to the factors outlined in the section below titled "Additional Business and Operational Updates", Opthea expects to complete patient recruitment in the Phase 3 clinical trials as early as the end of 2023, with top-line data to be reported when all patients complete the 52-week treatment period for the primary analysis. The primary efficacy and safety analysis from the Phase 3 studies will begin once the data entry for all patients at all sites has been completed, the data has been cleaned and the database has been locked. The primary statistical analysis and review of the safety data will occur after database lock, with reporting of top-line data to follow. If top-line results at the completion of the primary efficacy phase are favorable, Opthea intends to file for marketing approval for OPT-302 in 2026 for the treatment of wet AMD in the US, European Union and other territories.

Over the past six months, as the Phase 3 clinical trials have progressed, Opthea has increasingly focused on building the profile of the Company globally, by expanding its operations and building a US-based team of senior executives. In October 2022, Timothy Morris joined Opthea as Chief Financial Officer, based in the US. Mr. Morris has over 25 years of experience as the CFO for public biotechnology companies. During his career he has raised over US\$2 billion in equity and equity linked securities and has completed over 90 corporate transactions. Along with Opthea's Chief Executive Officer Dr. Baldwin, Mr. Morris will lead the effort to increase investor awareness in the US and globally. Recently Opthea has hired an Executive Director of Human Resources to assist in the execution of the hiring plan for US-based medical and clinical employees.

During the previous year, Opthea continued to increase the awareness of the Company through the attendance, participation and presentation at ophthalmology conferences around the world. Highlights of these efforts over the last six months included an update on OPT-302 delivered by Dr. Baldwin, at the American Academy of Ophthalmology Meeting in Chicago, Illinois, and a presentation on OPT-302 including a review of the phase 2b data, by Caroline Baumal, MD from the Tufts University School of Medicine, New England Eye Center, Boston Massachusetts at the annual FLORetina congress 2022 held in Rome Italy. The results of Phase 2b study were published in Ophthalmology, the Journal of the American Academy of Ophthalmology, in February 2023.

#### INTELLECTUAL PROPERTY

With respect to OPT-302, Opthea owns a patent family with two issued US patents, an issued European patent validated in 38 countries and non-US patents granted in Australia, Canada, China, Colombia, Indonesia, Israel, India, Japan, South Korea, Mexico, Malaysia, New Zealand, Russia, Singapore and South Africa, pending patent applications in Brazil and Philippines and pending divisional or continuation applications in the US, Europe and Malaysia. The patents have claims covering the composition of matter of OPT-302 and its use in treating disorders involving neovascularization, including eye diseases such as wet AMD and diabetic macular edema. There are also claims to nucleic acids, vectors, and host cells for producing OPT-302. These issued patents and pending patent applications, if issued, have a patent term to 2034, with additional data and market exclusivity periods which may apply.

Opthea owns another granted patent relating to soluble VEGFR-3 molecules which includes composition of matter claims to soluble VEGFR-3 molecules (such as OPT-302) which is in the US only, expiring November 2026, with corresponding applications in Australia, Canada, Europe and Japan having already expired in 2022.

## INVESTOR RELATIONS

Over the past six months, on the heels of the DFA with Launch Tx and the concurrent equity financing, Opthea has continued to raise the profile of its technology and Phase 3 clinical development program to both the international and local investment community. Opthea regularly presents and meets with global institutional and retail investors through investor meetings and forums. In August 2022, Opthea presented at the H.C. Wainwright Ophthalmology Virtual Conference. In November 2022, Opthea presented at the Jefferies Healthcare Conference in London. In December 2022, Opthea participated in a call sponsored by MST Access with leading ophthalmology expert, Dr. Jason Slakter, a clinical professor of Ophthalmology at New York University School of Medicine. In addition, Opthea met with investors in San Francisco as part of the J.P. Morgan Healthcare Conference activities in January 2023. Participation in investor conferences include the virtual presentations at the SVB Leerink Global Healthcare Conference in February 2023 and the Oppenheimer & Co Annual Healthcare conference in March 2023.

#### SUBSEQUENT EVENTS

No other matters or circumstances have arisen since the end of the reporting period, not otherwise disclosed in this report, which significantly affect, the operations of the Group, the results of those operations, or the state of affairs of the Group in future financial years.

### **Future developments**

Opthea continues to advance the clinical development of OPT-302 to key clinical and commercial milestones through Phase 3 and commercial manufacturing activities, regulatory engagement, and execution of the Company's Phase 3 pivotal trials in wet AMD.

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

### **WET AMD**

- Complete enrollment in the wet AMD Phase 3 ShORe and COAST clinical trials;
- Continue to manufacture current Good Manufacturing Practice (cGMP), clinical grade OPT-302 for use in Phase 3 clinical trials; and
- Progress manufacturing activities to support commercial supply of OPT-302.

#### **CORPORATE**

- Complete hiring of medical and clinical personnel to broaden Opthea's geographical reach by continuing to build US-based operations;
- Ensure the global investment and pharmaceutical/biotechnology community is aware of the commercial potential inherent in OPT-302 and the resultant value of Opthea;
- Continue preparation for OPT-302 commercialization; and
- Prepare for various opportunities to advance further development and commercialization of OPT-302 through engagement with pharmaceutical/biotechnology companies.

On behalf of the Directors

Jeremy Levin Chairman

February 23, 2023

# Additional Business and Operational Updates

#### **Risk Factors**

Investing in our securities involves a high degree of risk. You should consider and read carefully all of the factors, including potential uncertainties described below, as well as the Risk Factors included in our 20-F filing for the fiscal year ending June 30, 2022 as filed with the Securities and Exchange Commission on September 29, 2022, including our condensed financial statements and related notes included elsewhere in this Half-Year Report. If any of the risks and uncertainties described under Risk Factors included in our 20-F for the fiscal year ended June 30, 2022 or the following uncertainties actually occur, it could harm our business, prospects, results of operations and financial condition. In such event, the trading price of the ordinary shares and the ADSs could decline, and you might lose all or part of your investment. You should not interpret our disclosure of any of the risks and uncertainties described under Risk Factors included in our 20-F for the fiscal year ended June 30, 2022 or the following uncertainties to imply that such risks have not already materialized.

#### IMPACT OF COVID-19 AND MACROECONOMIC ENVIRONMENT

Opthea closely monitored how the COVID-19 situation affected its employees, business, investor relations, manufacturing, and clinical trials. In response to the COVID-19 pandemic, the Company followed the recommendations of the applicable State Government and when required, all its employees transitioned to working remotely and travel was restricted. These restrictions have since lifted but the Company continues to monitor the COVID-19 situation in Australia and abroad. While the pandemic appears to have waned, there may be significant uncertainty resulting from any changes with regards to COVID-19 infections, along with the impact of other macroeconomic factors such as inflation, supply chain issues, rising interest rates, and the impact of the Russian/Ukraine conflict. The impact of related responses and disruptions caused by the COVID-19 pandemic as well as prevailing macroeconomic factors has and may in the future 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 future COVID-19 outbreaks and macroeconomic factors on Opthea's 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, travel restrictions and social distancing in Australia, the US and other countries, specifically those where Opthea has clinical trial sites, business closures or business disruptions, the ultimate impact on financial markets and the global economy and the effectiveness of actions taken in Australia, the US and other countries to contain and treat the disease is unknown. In addition, actual or anticipated changes in interest rates and economic inflation and the impact of the Russian/Ukraine conflict has caused higher prices of supplies, declines in global confidence and disruption in the global credit and financial markets, which could make any necessary financing more difficult, more costly or more dilutive.

# Additional Business and Operational Updates continued

# DEVELOPMENT FUNDING AGREEMENT, FINANCIAL RESOURCES AND TIMING OF THE COMPLETION OF THE CLINICAL TRIALS

As described in the Operational update in the Directors Report the Company had US\$142 million of cash at December 31, 2022. Opthea believes that it will be able to fund its operating and research and development expenses through at least the fourth calendar quarter of 2024, including with additional funding expected to be available to Opthea under the DFA. The amounts and timing of Opthea's expenditures will depend upon and have been impacted in the past, and may continue to be impacted by, numerous factors, including historical or future delays in completing our clinical trials, particularly as it relates to enrollment, the timing of regulatory submissions, the performance and cost efficiency of contract research organizations ("CROs") and the continuing impacts of the COVID-19 pandemic, the global supply chain and macroeconomic challenges. In particular, delays in patient enrollment have in the past resulted, and may in the future result in increased costs or delays and other impacts on the timing of our Phase 3 clinical trials. Opthea has based this estimate on assumptions that may prove to be wrong, and Opthea could exhaust its available capital resources sooner than it expects. Opthea may also experience future delays in its clinical development or commercialization of OPT-302 for wet AMD, including due to factors and conditions set forth above or other factors that Opthea cannot presently anticipate. Opthea intends to focus its development efforts on achieving commercialization of OPT-302 for the treatment of wet AMD, and Opthea will require additional funding to reach commercialization of OPT-302 in any indication, including wet AMD. In addition, Opthea may require additional external funding to meet the minimum cash condition under the DFA, including prior to the readout of top-line results for Opthea's Phase 3 clinical trials for OPT-302 for the treatment of wet AMD, particularly if Opthea experiences delays in its Phase 3 clinical trials.

Opthea may receive potential future payments under the DFA but there can be no assurance that Opthea will meet the conditions under the DFA to receive any future payments, some of which are payable at the Investor's discretion. Opthea does not have any other committed external source of funds and expects to finance future cash needs through public or private equity or debt offerings or collaborations. However, the DFA limits the type of financing Opthea may pursue in the future and Opthea may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. In February 2022, Opthea established an "at the market" program (the "ATM Program") with Jefferies LLC ("Jefferies"). Pursuant to the ATM Program, Opthea may offer and sell up to US\$75 million of its ordinary shares in the form of American Depositary Shares ("ADSs"), with each ADS representing eight ordinary shares, through Jefferies. Opthea has not sold any ordinary shares under the ATM Program. If Opthea raises additional capital, this may cause dilution to holders of the Company's ordinary shares and American Depositary Shares. Opthea may also raise additional capital, including through dilutive equity financings, opportunistically to supplement capital that may be available under the DFA and to further support its clinical trials for OPT-302.

# Auditor's Independence Declaration

# Deloitte.

Deloitte Touche Tohmatsu ABN 74 490 121 060

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

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

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

23 February 2023

Dear Board Members

#### Opthea Limited

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

As lead audit partner for the review of the financial statements of Opthea Limited for the half year ended 31 December 2022, I declare that to the best of my knowledge and belief, there have been no contraventions of:

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

Yours sincerely

Deloirre Tomme Tommarsu

DELOITTE TOUCHE TOHMATSU

Vincent Snijders

Partner

**Chartered Accountant** 

Deloitte refers to one or more of Deloitte Touche Tohmatsu Limited ("DTTL"), its global network of member firms, and their related entities (collectively, the "Deloitte organisation"). DTTL (also referred to as "Deloitte Global") and each of its member firms and related entities are legally separate and independent entities, which cannot obligate or bind each other in respect of third parties. DTTL and each DTTL member firm and related entity is liable only for its own acts and omissions, and not those of each other. DTTL does not provide services to clients. Please see www.deloitte.com/about to learn more.

Member of Deloitte Asia Pacific Limited and the Deloitte organisation

©2023 Deloitte Touche Tohmatsu

# Condensed Consolidated Statement of Profit or Loss and Other Comprehensive Income

# For the half year ended December 31, 2022

		Decem	ber 31
	Note	2022 US\$	2021 US\$
Revenue		52,107	45,048
Other income		144,961	108,322
Research and development expenses		(61,433,565)	(31,819,649)
Administrative expenses		(14,639,452)	(5,199,088)
Non-cash interest expense DFA	11	(3,480,696)	-
Share-based payments expense		(2,852,378)	(2,443,221)
Patent and intellectual property expenses		(81,621)	(36,847)
Finance income – interest income		1,107,859	91,218
Net foreign exchange gain/(loss)	5	2,039,030	(1,375,143)
Loss before income tax		(79,143,755)	(40,629,360)
Income tax benefit	6	2,044,739	2,916,601
Loss for period		(77,099,014)	(37,712,759)
Other comprehensive income			
Items that will not be subsequently reclassified to profit or loss:			
Fair value gains on investments in financial assets		_	-
Other comprehensive income for the period		-	=
Total comprehensive loss for the period		(77,099,014)	(37,712,759)
Earnings per share for loss attributable for the ordinary equity holders of the parent:			
Basic and diluted loss per share (cents)		(16.51)	(10.74)

# Condensed Consolidated Statement of Financial Position

# As at December 31, 2022

	Note	December 31 2022 US\$	June 30 2022 US\$
Current Assets			
Cash and cash equivalents	7	141,772,429	44,631,293
Current tax receivable		8,344,025	6,299,286
Receivables		811,457	257,668
Prepayments	8	2,764,808	8,720,195
Total current assets		153,692,719	59,908,442
Non-current assets			
Plant and equipment		27,797	28,082
Right-of-use assets	9	210,564	_
Prepayments		77,267	110,295
Total non-current assets		315,628	138,377
Total assets		154,008,347	60,046,819
Current liabilities			
Payables		8,673,587	11,445,498
Lease liabilities	10	84,314	_
Provisions		658,368	596,203
Total current liabilities		9,416,269	12,041,701
Non-current liabilities			
Lease liabilities		126,339	_
Financial liabilities	10	87,980,696	_
Provisions		17,447	27,974
Total non-current liabilities		88,124,482	27,974
Total liabilities		97,540,751	12,069,675
Net assets		56,467,596	47,977,144
Equity			
Contributed equity: ordinary shares	12	320,586,080	235,277,217
Accumulated losses	14	(294,040,367)	(216,941,353)
Reserves	13	29,921,883	29,641,280
Total equity	10	56,467,596	47,977,144
Total equity		30,707,370	7,,,,,,,,

# Condensed Consolidated Statement of Changes in Equity

# For the half year ended December 31, 2022

	Contributed equity US\$	Share-based payments reserve US\$	Fair value of investments reserve US\$	FX translation reserve US\$	Accumulated losses US\$	Total equity US\$
At July 1, 2022	235,277,217	8,466,706	1,085,411	20,089,163	(216,941,353)	47,977,144
Loss for the period	-	_	-	_	(77,099,014)	(77,099,014)
Total comprehensive income and expense for the period	-	-	-	-	(77,099,014)	(77,099,014)
Issue of ordinary shares (net of costs US\$8,184,643)	81,815,357	-	-	-	-	81,815,357
Recognition of share-based payment	-	2,852,378	-	-	-	2,852,378
Issue of ordinary shares on conversion of LTIP	3,493,506	(2,571,775)	-	-	_	921,731
Balance at December 31, 2022	320,586,080	8,747,309	1,085,411	20,089,163	(294,040,367)	56,467,596
At July 1, 2021	234,147,526	4,087,650	1,085,411	20,089,163	(124,123,982)	135,285,768
Loss for the period		_			(37,712,759)	(37,712,759)
Total comprehensive income and expense for the period	-	-	-	-	(37,712,759)	(37,712,759)
Recognition of share-based payment		2,443,221	-	-	-	2,443,221
Issue of ordinary shares one conversion of LTIP	491,704	(234.530)	-	_		257,174
Balance at December 31, 2021	234,639,230	6,296,341	1,085,411	20,089,163	(161,836,741)	100,273,404

# Condensed Consolidated Statement of Cash Flows

# For the half year ended December 31, 2022

	Decem	ber 31
	2022 US\$	2021 US\$
Cash flows from operating activities		
Interest received	860,604	100,757
Royalty and license income received	52,107	1,570
Grant and other income received	141,301	_
Payment of lease interest	(2,661)	(2,960)
Payments to suppliers, employees and for research and development and intellectual property costs (inclusive of GST)	(70,337,710)	(33,826,440)
Research and development tax incentive scheme received	_	4,972,898
Net cash flows used in operating activities	(69,286,359)	(28,754,175)
Cash flows from investing activities  Purchase of plant and equipment	(7,019)	(1,651)
Net cash flows (used in)/provided by investing activities	(7,019)	(1,651)
Cash flows from financing activities		
Payment of lease liabilities	(42,025)	(45,714)
Net proceeds on issue of ordinary shares	81,815,357	-
Net proceeds from DFA	84,500,000	
Cash received for ordinary shares issued on exercise of options	921,731	257,174
Net cash flows provided by financing activities	167,195,063	211,460
Net increase in cash and cash equivalents	97,901,685	(28,544,366)
Effect of foreign exchange rate changes	(760,549)	(1,375,143)
Cash and cash equivalents at beginning of the period	44,631,293	118,193,177
Cash and cash equivalents at end of the period	141,772,429	88,273,668

## For the half year ended December 31, 2022

### 1. Corporate Information

The consolidated financial report of Opthea Limited (the 'Group'), for the half year ended December 31, 2022 was authorized for issue in accordance with a resolution of the directors on February 23, 2023.

Opthea Limited ("the Parent") is a company limited by shares incorporated in Australia whose ordinary shares are publicly traded on the Australian Securities Exchange (ASX) and whose American Depository Shares (ADSs) are listed on the NASDAQ.

## 2. Adoption of new and revised Australian Accounting Standards

The half year condensed consolidated financial statements have been prepared using the same accounting policies as used in the annual financial statements for the year ended June 30, 2022.

There were no changes in accounting policy during the half year ended December 31, 2022, nor did the introduction of new accounting standard lead to any changes in measurement or disclosure in these financial statements.

The Group has not adopted any accounting standard that are issued but not yet effective. Significant accounting policies that summarize the measurement basis used and are relevant to an understanding of the financial statements are provided in the annual financial report.

## 3. Significant accounting policies

#### **BASIS OF PREPARATION**

These condensed consolidated financial statements have been prepared on the basis of historical cost, except for the revaluation of certain non-current assets and financial instruments. Cost is based on the fair values of the consideration given in exchange for assets. All amounts are presented in United States Dollars, unless otherwise noted.

The accounting policies and methods of computation adopted in the preparation of the half-year financial report are consistent with those adopted and disclosed in the Company's 2022 annual financial report for the financial year ended June 30, 2022. The accounting policies are consistent with Australian Accounting Standards and with International Financial Reporting Standards.

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

### **Presentation currency**

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

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

#### CHANGE IN PRESENTATION OF OTHER INCOME

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

#### **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; and
- 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.

## 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 December 31, 2022, the Group is in the research phase and has not capitalized any development costs to date.

### 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 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.

#### **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).

#### 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 AASB 16. This expense is presented within "administrative expenses" in the Consolidated Statement of Profit or Loss and Other Comprehensive Income.

#### Financial liabilities

Financial liabilities are recognized in the Group's statement of financial position when the Group becomes a party to the contractual provisions of the instrument.

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

#### Amortised cost and effective interest method

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

Interest expense is recognized in profit and loss and is included in the "Non cash interest expense" line item.

## 4. Operating segments

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

The Group is focused primarily on developing a novel therapy for the treatment of highly prevalent and progressive retinal diseases.

The Chief Executive Officer regularly reviews entity wide information that is compliant with Australian Accounting Standards. There is only one segment for segment reporting purposes, and the information reviewed by the Chief Executive Officer for the purpose of resources allocation and performance assessment is the same as the information presented in the consolidated financial statements.

Its only revenue stream in the current half year is royalty income generated from licenses granted in respect of the Group's intellectual property that are unrelated to its 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 for the half year ended December 31, 2022 of US\$52,107 (December 31, 2021: US\$45,048) was generated from customers based outside Australia. The Group does not have any major customers. The majority of property, plant and equipment is located in Australia.

## 5. Net foreign exchange gain/(loss)

	2022 US\$	2021 US\$
Net foreign exchange gains/(losses)	2,039,030	(1,375,143)
	2,039,030	(1,375,143)

### 6. Income tax

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

	2022 US\$	2021 US\$
Accounting loss before tax	(79,143,754)	(40,629,360)
At the parent entity's statutory income tax rate of 30%	23,743,126	12,188,808
Research and development tax incentive on eligible expenses	2,044,739	2,916,601
Non-deductible R&D expenditure	(1,410,165)	(2,011,449)
Other non-deductible expenses – share-based payment expense	(855,713)	(732,966)
Amount of temporary differences and carried forward tax losses not recognized	(21,477,248)	(9,444,393)
Income tax benefit reported in the Statement of Profit or Loss and Other Comprehensive Income	2,044,739	2,916,601

# 7. Cash and cash equivalents

	December 31 2022 US\$	June 30 2022 US\$
For the purpose of the half year statement of cash flows, cash and cash equivalents are comprised of the following:		
Cash at bank and in hand	46,575,077	11,853,883
Short-term deposits	95,197,352	32,777,410
	141,772,429	44,631,293

Cash at bank earns interest at floating rates based on daily bank deposit rates.

Short-term deposits are with major Australian banks and are made for varying periods of between 62 days and 93 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 period end, the average rate was 3.87% (2021 half year: 0.22%).

# <sup>□</sup>8. Prepayments

	December 31 2022 US\$	June 30 2022 US\$
R&D Contract Research Organization	824,030	7,428,599
Insurance	1,734,328	1,086,847
Other prepayments	206,450	204,749
	2,764,808	8,720,195

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, start patient recruitment and operationally manage the trials. These prepayments covered the activation of sites of the Phase 3 clinical trials and other key milestones and are expected to be consumed within the next 12 months. The insurance amount relates to specific Phase 3 Clinical trial insurance in place for various sites around the world covering periods to the end of 2024, as well as D&O insurance. The non-current portion of the prepayments are recorded as non-current assets which relates specifically to Phase 3 clinical trial insurance.

## 9. Right-of-use assets

	2022 US\$	2022 US\$
Right-of-use asset cost		
Opening balance	281,554	251,189
Additions	252,677	-
Exchange on translation	_	30,365
	534,231	281,554
Accumulated depreciation		
Opening balance	(281,554)	(83,729)
Charge for the period	(42,113)	(185,508)
Exchange on translation	_	(12,317)
	(323,667)	(281,554)
Net carrying amount	210,564	_

December 31

June 30

The Group leases its main office accommodation for employees. The term of the lease is three years and is the renewal of a lease for the same premises that expired on July 15, 2022. The lease does not include the option to extend the term of the lease on expiry.

The maturity analysis of lease liabilities is presented in note 10.

	2022 US\$	2021 US\$
Amounts recognized in profit or loss		
Depreciation expense on right-of-use asset	42,113	69,197
Lease finance costs	2,661	3,556
Expense relating to leases of low value assets	3,034	4,835
	47,808	77,588

### 10. Lease liabilities

	December 31 2022 US\$	June 30 2022 US\$
Carrying amount at July 1	-	182,290
New Lease	252,678	_
Payments	(42,025)	(182,290)
Carrying amount at December 31/June 30	210,653	_
Maturity analysis:		
Year 1	86,975	_
Year 2	129,000	_
	215,975	_
Less: unearned interest	(5,322)	_
	210,653	_
Analyzed into:		
Current portion	84,314	_
Non-current portion	126,339	_
	210,653	_

## 11. Financial liabilities

	December 31 2022 US\$	June 30 2022 US\$
Carrying amount at July 1	-	-
Funding at fair value	84,500,000	_
Amortized interest	3,480,696	
Carrying amount at December 31/June 30	87,980,696	_

Pursuant to the DFA, Launch Tx has committed to provide Opthea US\$120 million in funding which may be increased up to US\$170 million at their option, of which US\$50 million (net of US\$0.5 million of funding costs) was paid in September. Opthea received the proceeds from the first tranche of the DFA, with the remainder being funded in two additional tranches: one paid on December 31, 2022 and one to be paid on or before December 31, 2023. Pursuant to the DFA, Opthea is required to use commercially reasonable efforts to develop OPT-302 for the treatment of wet AMD in accordance with the DFA, including pursuant to certain development timelines set forth therein.

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

Under AASB 9 and AASB 132, this arrangement is recorded as a Financial Liability as the payments are dependent on future events, namely the approval of OPT-302 in a Major Market, and Opthea is not in control of these future events. The arrangement was initially recorded at the fair value of the net proceeds received in October and December 2022, US\$84.5 million. In subsequent reporting periods the Financial Liabilities will be recorded at an amortized cost basis using the effective interest method. An effective interest rate is calculated at inception and will take into account the contractual repayment terms both fixed and variable (as a percentage of future revenues of OPT-302) and an estimated repayment period. An effective interest rate of approximately 24% was calculated at inception and was used to record interest expense of US\$3.6 million for the six months ending December 31, 2022. The effective interest rate was based on the recorded fair value of payments received and discounting estimated future cash payments over the expected life of the financial liability. The effective interest rate will not change over the life of this Liability. The company will continue to record a non-cash interest expense in its Consolidated Statements of Comprehensive Loss over the term of the DFA.

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

## 12. Contributed equity

	December 31 2022 US\$	June 30 2022 US\$
(A) ORDINARY SHARES		
Issued and fully paid at December 31/June 30	320,586,080	235,277,217
Movement in ordinary shares:		
Opening balance	235,277,217	234,147,526
Issue of shares on exercise of options granted under the LTIP	3,493,506	1,129,691
Issue of shares from Equity financing	81,815,357	
	320,586,080	235,277,217
Ordinary shares on issue:	No:	No:
Opening balance	352,152,542	351,003,541
Issue of shares on exercise of options granted under the LTIP	2,146,852	1,149,001
Issue of shares from Equity Financing	112,619,066	
	466,918,460	352,152,542

Issued capital of ordinary shares at December 31, 2022 amounted to US\$320,586,080 (466,918,460 fully paid ordinary shares) net of share issue costs and tax. The Company issued 112,619,066 shares net of issue costs in respect of the two equity financing tranches and the Share Purchase Plan in August and September 2022.

## 13. Reserves

	December 31 2022 US\$	June 30 2022 US\$
Fair value of investments reserve <sup>1</sup>	1,085,411	1,085,411
Share-based payments reserve <sup>2</sup>	8,747,308	8,466,706
Foreign currency translation reserve <sup>3</sup>	20,089,163	20,089,163
Total reserves	29,921,882	29,641,280
1. Movement in fair value of investments reserve:		
Opening balance	1,085,411	1,085,411
Fair value gains on investments in financial assets	_	_
Exchange on translation	_	_
Closing balance	1,085,411	1,085,411
2. Movement in share-based payments reserve:		
Opening balance	8,466,706	4,087,650
Share-based payments expense	2,852,378	5,251,572
Exercise of options	(2,571,776)	(872,516)
Closing balance	8,747,308	8,466,706
3. Movement in foreign currency translation reserve:		
Opening balance	20,089,163	20,089,163
(Gains)/loss on translation	_	-
Closing balance	20,089,163	20,089,163

- 1. Fair value of Investments reserve: This reserve records fair value changes on listed investments.
- 2. 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.
- 3. Movement in foreign currency translation reserve: The reserve records the value of foreign currency movements on translation of financial statements from A\$ to US\$.

### 14. Commitments

## (i) RESEARCH COMMITMENTS

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

	December 31 2022 US\$	June 30 2022 US\$
Within one year	48,206,383	39,947,900
After one year but not more than five years	3,031,554	8,007,202
After more than five years	45,000	45,000
	51,282,937	48,000,102

Currently, the largest contract has a 60-day termination clause and commitments have been limited to twelve-months under this contract.

### (ii) COMMERCIAL COMMITMENTS

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

Docombox 31

June 30

	2022 US\$	2022 US\$
Within one year	180,548	507,874
After one year but not more than five years	-	_
After more than five years	-	
	180,548	507,874

## 15. Events subsequent to reporting date

No other matters or circumstances have arisen since the end of the reporting period, not otherwise disclosed in this report, which significantly affected, or may significantly affect, the operations of the Group, the results of those operations, or the state of affairs of the Group in future financial years.

# Forward Looking Statements

Certain statements in this report may contain forward-looking statements, including within the meaning of the US Private Securities Litigation Reform Act of 1995. Any statement describing Company goals, expectations, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement, including, but not limited to, the Company's expectations for the period for which the Company is able to fund its operating and research and development expenses, the timing of the Company's clinical trials, and the key objectives of the Company as described under "Future Developments". Such statements are based on Opthea's current plans, objectives, estimates, expectations, and intentions and are subject to certain risks and uncertainties, including risks and uncertainties associated with clinical trials and product development, Opthea's ability to obtain funding for its operations, including funding necessary to complete further development and commercialization of its product candidates, and the impact of general economic, industry or political conditions in Australia, the United States or internationally. These and other risks and uncertainties are described more fully in the section titled "Risk Factors" in Opthea's Annual Report on Form 20-F filed with the SEC on September 29, 2022.

The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required under applicable law. You should not place undue reliance on these forward-looking statements as predictions of future events, which statements apply only as of the date of this report. Actual results could differ materially from those discussed in this report.

# Directors' Declaration



- (a) in the Directors' opinion, there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable; and
- (b) in the Directors' opinion, the attached financial statements and notes thereto are in accordance with the *Corporations Act 2001*, including compliance with accounting standards and giving a true and fair view of the financial position and performance of the consolidated entity.

Signed in accordance with a resolution of the Directors made pursuant to s.303(5) of the *Corporations Act 2001*. On behalf of the Directors

Jeremy Levin Chairman

Melbourne, February 23, 2023

# Independent Auditor's Review Report

# Deloitte.

Deloitte Touche Tohmatsu ABN 74 490 121 060

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

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

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

Report on the Half-Year Financial Report

#### Conclusion

We have reviewed the half-year financial report of Opthea Limited (the "Company") and its subsidiaries (the "Group"), which comprises the condensed consolidated statement of financial position as at 31 December 2022, and the condensed consolidated statement of profit or loss and other comprehensive income, the condensed consolidated statement of cash flows and the condensed consolidated statement of changes in equity for the half-year ended on that date, notes comprising a summary of significant accounting policies and other explanatory information, and the directors' declaration as set out on pages 11 to 26.

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the half-year financial report of Opthea Limited is not in accordance with the Corporations Act 2001, including:

- (a) giving a true and fair view of the Group's financial position as at 31 December 2022 and of its performance for the half-year ended on that date; and
- (b) complying with Accounting Standard AASB 134 Interim Financial Reporting and the Corporations Regulations 2001.

#### Basis for Conclusion

We conducted our review in accordance with ASRE 2410 Review of a Financial Report Performed by the Independent Auditor of the Entity. Our responsibilities are further described in the Auditor's Responsibilities for the Review of the Half-year Financial Report section of our report. We are independent of Opthea Limited in accordance with 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 annual 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 review report.

Directors' Responsibilities for the Half-year Financial Report

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

Deloitte refers to one or more of Deloitte Touche Tohmatsu Limited ("DTTL"), its global network of member firms, and their related entities (collectively, the "Deloitte organisation"). DTTL (also referred to as "Deloitte Global") and each of its member firms and related entities are legally separate and independent entities, which cannot obligate or bind each other in respect of third parties. DTTL and each DTTL member firm and related entity is liable only for its own acts and omissions, and not those of each other. DTTL does not provide services to clients. Please see www.deloitte.com/about to learn more.

Member of Deloitte Asia Pacific Limited and the Deloitte organisation

©2023 Deloitte Touche Tohmatsu

# Independent Auditor's Review Report continued

# Deloitte.

Auditor's Responsibilities for the Review of the Half-year Financial Report

Our responsibility is to express a conclusion on the half-year financial report based on our review. ASRE 2410 requires us to conclude whether we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the *Corporations Act 2001* including giving a true and fair view of the Group's financial position as at 31 December 2022 and its performance for the half-year ended on that date, and complying with Accounting Standard AASB 134 Interim Financial Reporting and the *Corporations Regulations 2001*.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Deloirre Tomme Tommarsu

**DELOITTE TOUCHE TOHMATSU** 

Vincent Snijders

Partner

Chartered Accountants Paramatta, 23 February 2023

# 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

Lawrence Gozlan Non-Executive Director

Julia Haller Non-Executive Director

Susan Orr Non-Executive Director

Quinton Oswald Non-Executive Director

Michael Sistenich Non-Executive Director

Daniel Spiegelman Non-Executive Director

#### **COMPANY SECRETARY**

Karen Adams BBus, CPA GAICD, FGIA FCG

#### **REGISTERED OFFICE**

Level 4, 650 Chapel Street South Yarra, Victoria 3141

#### **US OFFICE**

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

### PRINCIPAL ADMINISTRATIVE OFFICE

Level 4, 650 Chapel Street South Yarra, Victoria 3141

www.opthea.com

Telephone: +61 (3) 9826 0399

#### **BANKERS**

Commonwealth Bank of Australia Melbourne, Victoria

### **AUDITORS**

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

### **SOLICITORS**

Gilbert + Tobin Level 25, 101 Collins Street Melbourne, Victoria 3000

Cooley LLP 3175 Hanover Street, Palo Alto, CA, USA, 94304

#### **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") (Ticker: OPT).

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

