UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
OF THE SECURITIES EXCHANGE ACT OF 1934

For the month of February2024

Commission File No. 001-39621

OPTHEA LIMITED
(Translation of registrant's name into English)

Level 4
650 Chapel Street
South Yarra, Victoria, 3141
Australia
(Address of registrant's principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.
Form 20-F ☒ Form 40-F ☐

EXHIBIT INDEX

Exhibit	Description
99.1	**Press Release - Opthea Reports Half-Year Financial Results and Business Updates**
99.2	Half Year Report

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereto duly authorized.

OPTHEA LIMITED
(Registrant)

By: /s/ Frederic Guerard
Name: Frederic Guerard
Title: Chief Executive Officer

Date: 2/29/2024

Exhibit 99.1

ASX, Nasdaq and Media Release

29 February 2024

Opthea Reports Half-Year Financial Results and Business Updates

Enrollment completion of sozinibercept Phase 3 program for wet AMD expected in calendar year (CY) Q2 2024 with top-line data mid-CY 2025

Expanded U.S. leadership team with the appointments of Dr. Frederic Guerard as CEO, Peter Lang as CFO, and Dr. Arshad M. Khanani as Chief Medical Advisor

Cash and cash equivalents of $157.1 million as of December 31, 2023

Melbourne, Australia and Princeton, New Jersey; 29 February 2024 – Opthea Limited (ASX:OPT; NASDAQ:OPT; "Opthea"), a clinical-stage biopharmaceutical company developing novel therapies to treat highly prevalent and progressive retinal diseases, today announced financial results for the six months ended December 31, 2023 and highlighted recent corporate and clinical updates.

"It is a transformative time for Opthea. We substantially advanced the development of sozinibercept, our lead product candidate for the treatment of wet age-related macular degeneration (wet AMD), expanded our U.S. leadership team, strengthened our clinical and regulatory organization, and received US$143 million in funding. We recently announced the completion of enrollment in our first pivotal Phase 3 trial (COAST), in combination with EYLEA®(aflibercept)," said Frederic Guerard, PharmD, Chief Executive Officer of Opthea.

"We believe that sozinibercept has the potential to deliver superior vision gains for millions of people with wet AMD based on our Phase 2b trial results which demonstrated superior and statistically significant improvements in visual acuity for patients treated with sozinibercept in combination with LUCENTIS® (ranibizumab). Sozinibercept therefore has the potential to be the first product in more than 15 years to improve the standard of care in wet AMD and make a tangible difference in the lives of patients," continued Dr. Guerard.

Peter Lang, Chief Financial Officer of Opthea, added, "We are excited about Opthea's progress. Looking ahead, we expect to complete enrollment in our second Phase 3 trial (ShORe), in combination with the standard of care ranibizumab, in the second quarter of CY 2024. In addition, we intend to report the top-line data on the COAST and ShORe trials in mid-CY 2025. We are encouraged by the positive momentum in the sozinibercept program."

Anticipated Milestones

- **Enrollment completion** in the second Phase 3 pivotal ShORe trial evaluating sozinibercept in combination with ranibizumab, expected in Q2 CY 2024.
- **Top-line Phase 3 results**from the COAST and ShORe trials expected by mid-CY 2025.

Corporate Highlights

- In February 2024, **completed enrollment in the COAST Phase 3** pivotal trial evaluating sozinibercept in combination with aflibercept**.**
- In February 2024, **Dr. Arshad M. Khanani, FASRS, a global retina expert joined as Chief Medical Advisor**to support sozinibercept development and launch preparation.
- In February 2024, strengthened the organization with **key clinical and regulatory hires** including Dr. Julie Clark as SVP, Clinical Development, and Dr. Fang Li as SVP, Regulatory Affairs.
- In December 2023, Opthea received **US$85 million** in non-equity funding consisting of the remaining US$35 million from the previously announced Development Funding Agreement (DFA) with Carlyle and its life science franchise, Abingworth, and an additional US$50 million under an amended DFA with a new co-investor.
- In October 2023, **appointed U.S.-based leadership team** with Dr. Frederic Guerard as Chief Executive Officer and Peter Lang, MBA, as Chief Financial Officer and the transition of Dr. Megan Baldwin to the role of Founder, Chief Innovation Officer.
- In August 2023, Opthea successfully completed a private placement and rights equity offering raising **A$90 million** (**US$58 million)** in Australia.

Financial Results

- US$157.1 million in cash and cash equivalents, as of December 31, 2023.
- Operating Expenses (Research and Development, Patent and Intellectual Property, and Administrative Expenses) totaled US$93.9 million for the six months ended December 31, 2023, up 19% compared to the prior year period, primarily driven by progress in the pivotal Phase 3 clinical program and chemistry, manufacturing, and controls (CMC) activities.
- Net Cash Flows Used in Operating Activities for the six months ended December 31, 2023 ended at ($69.4) million, a slight increase from ($69.3) million for the prior year period.

Upcoming Events

- Leerink Partners Global Biopharma Conference 2024, March 11-13, 2024

See Opthea's 2024 Half Year FY Report as lodged today on ASX and filed as an exhibit to the Form 6-K furnished with the U.S. Securities and Exchange Commission (the "SEC") on February

29, 2024, for more detailed information, which report can be accessed without charge at www.sec.gov. A copy can also be accessed under the investor section of the www.opthea.comwebsite.

About Sozinibercept

Sozinibercept (OPT-302) is a soluble form of vascular endothelial growth factor receptor 3 (VEGFR-3) expressed as an immunoglobulin G1 (IgG1) Fc-fusion protein. It binds and neutralizes the activity of VEGF-C and VEGF-D on their endogenous receptors, VEGFR-2 and VEGFR-3. Research indicates that targeted inhibition of VEGF-C and VEGF-D can prevent blood vessel growth and vascular leakage, which contribute to the pathophysiology of retinal diseases including wet AMD. Sozinibercept has received Fast Track Designation from the U.S. FDA for the treatment of wet AMD.
Positive results from the Phase 2b study of sozinibercept, administered in combination with standard of care, LUCENTIS® (ranibizumab), for the treatment of wet AMD, published in *Ophthalmology*, met the pre-specified primary efficacy endpoint of a statistically superior gain in visual acuity at 24 weeks, compared to ranibizumab alone. In addition, secondary outcomes were positive for the combination therapy with sozinibercept, including more participants with gains in vision of 10 or more letters and improved anatomy, with a reduction in swelling and vascular leakage, with a favorable safety profile.

About Opthea

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, sozinibercept,is being evaluated in two pivotal Phase 3 clinical trials (COAST, NCT04757636and ShORe, NCT04757610) for use in combination with standard-of-care anti-VEGF-A monotherapies to improve overall efficacy and deliver superior vision gains compared to the standard-of-care anti-VEGF-A agents. To learn more, visit www.opthea.com and follow us on X and LinkedIn.

EYLEA®is a registered trademark of Regeneron Pharmaceuticals, Inc.
LUCENTIS®is a registered trademark of Genentech USA, Inc. A member of the Roche Group.

Inherent risks of Investment in Biotechnology Companies

There are a number of inherent risks associated with the development of pharmaceutical products to a marketable stage. The lengthy clinical trial process is designed to assess the safety and efficacy of a drug prior to commercialization and a significant proportion of drugs fail one or both of these criteria. Other risks include uncertainty of patent protection and proprietary rights, whether patent applications and issued patents will offer adequate protection to enable product development, the obtaining of necessary drug regulatory authority approvals and difficulties caused by the rapid advancements in technology. Companies such as Opthea are dependent on the success of their research and development projects and on the ability to attract funding to support these activities. Investment in research and development projects cannot be assessed

on the same fundamentals as trading and manufacturing enterprises. Therefore, investment in companies specializing in drug development must be regarded as highly speculative. Opthea strongly recommends that professional investment advice be sought prior to such investments.

Forward-looking Statements

This ASX announcement contains certain forward-looking statements, including within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. The words “expect”, “believe,” “should”, “could”, “may”, “will”, “plan” and other similar expressions are intended to identify forward-looking statements. Forward-looking statements in this ASX announcement include statements regarding expectations on the outcomes of Opthea’s Phase 3 clinical trials of sozinibercept, the potential for sozinibercept as a combination therapy to be the first therapy to achieve superior visual outcomes over anti-VEGF-A monotherapy and improve vision outcomes for patients with wet AMD, the expected timing for completion of enrollment for ShORe and topline data for Opthea’s Phase 3 clinical trials of sozinibercept, the market opportunity for sozinibercept, and the future performance of Opthea. Forward-looking statements, opinions and estimates provided in this ASX announcement are based on assumptions and contingencies which are subject to change without notice, as are statements about market and industry trends, which are based on interpretations of current conditions. Forward-looking statements are provided as a general guide only and should not be relied upon as an indication or guarantee of future performance. They involve known and unknown risks and uncertainties and other factors, many of which are beyond the control of Opthea and its directors and management and may involve significant elements of subjective judgment and assumptions as to future events that may or may not be correct. These statements may be affected by a range of variables which could cause actual results or trends to differ materially, including but not limited to future capital requirements, the development, testing, production, marketing and sale of drug treatments, regulatory risk and potential loss of regulatory approvals, ongoing clinical studies to demonstrate sozinibercept safety, tolerability and therapeutic efficacy, additional analysis of data from Opthea’s Phase 3 clinical trials, timing of completion of ShORe clinical trial patient enrollment and clinical research organization and labor costs, intellectual property protections, and other factors that are of a general nature which may affect the future operating and financial performance of the Company including risk factors set forth in Opthea’s Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission (the “SEC”) on September 28, 2023, Opthea’s 2024 Half Year Report included as an exhibit to the Form 6-K filed with the SEC on February 29, 2024, and other future filings with the SEC. Actual results, performance or achievement may vary materially from any projections and forward-looking statements and the assumptions on which those statements are based. Subject to any continuing obligations under applicable law or any relevant ASX listing rules, Opthea disclaims any obligation or undertaking to provide any updates or revisions to any forward-looking statements in this ASX announcement to reflect any change in expectations in relation to any forward-looking statements or any change in events, conditions or circumstances on which any such statement is based, except as otherwise required by applicable law.

Authorized for release to ASX by Fred Guerard, CEO

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February 29, 2024

Half-Year Financial Report December 31, 2023

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, 2023. The previous corresponding periods are the fiscal year ended June 30, 2023 and the half year ended December 31, 2022.

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, 2023.

Karen Adams
Company Secretary

Appendix 4D

Half-Year Financial Report

Opthea Limited ABN 32 006 340 567

REPORTING PERIOD: HALF YEAR ENDED DECEMBER 31, 2023
PREVIOUS CORRESPONDING PERIOD: HALF YEAR ENDED DECEMBER 31, 2022

Index

This half-year report should be read in conjunction with the Company's 2023 Annual Report and form 20-F FY2023.

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

Except with respect to US dollar amounts presented as contractual terms, amounts are 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, 2023. 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 date. 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.

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 ® and ™ 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.

Appendix 4D (cont.)

Results for announcement to the market

The consolidated results of Opthea Limited for the six months ended December 31, 2023 are as follows:

Revenues and results from ordinary activities

		Changes compared to: December 31 2022 %		December 31 2023 US$
Revenues from ordinary activities	Increased	17%	to	60,798
Loss from ordinary activities before tax	Loss has increased	28%	to	(101,223,489)
Loss from ordinary activities after tax attributable to members	Loss has increased	25%	to	(96,185,431)

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

Shareholder distribution

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

Net tangible assets per share

	Consolidated	
NTA BACKING	December 31 2023 US$	June 30 2023 US$
Net tangible asset backing per ordinary security	($0.07)	($0.01)

Status of review of accounts

The financial report for the half year ended December 31, 2023 has been reviewed. The auditor's review report is included at page 31 of the financial report.

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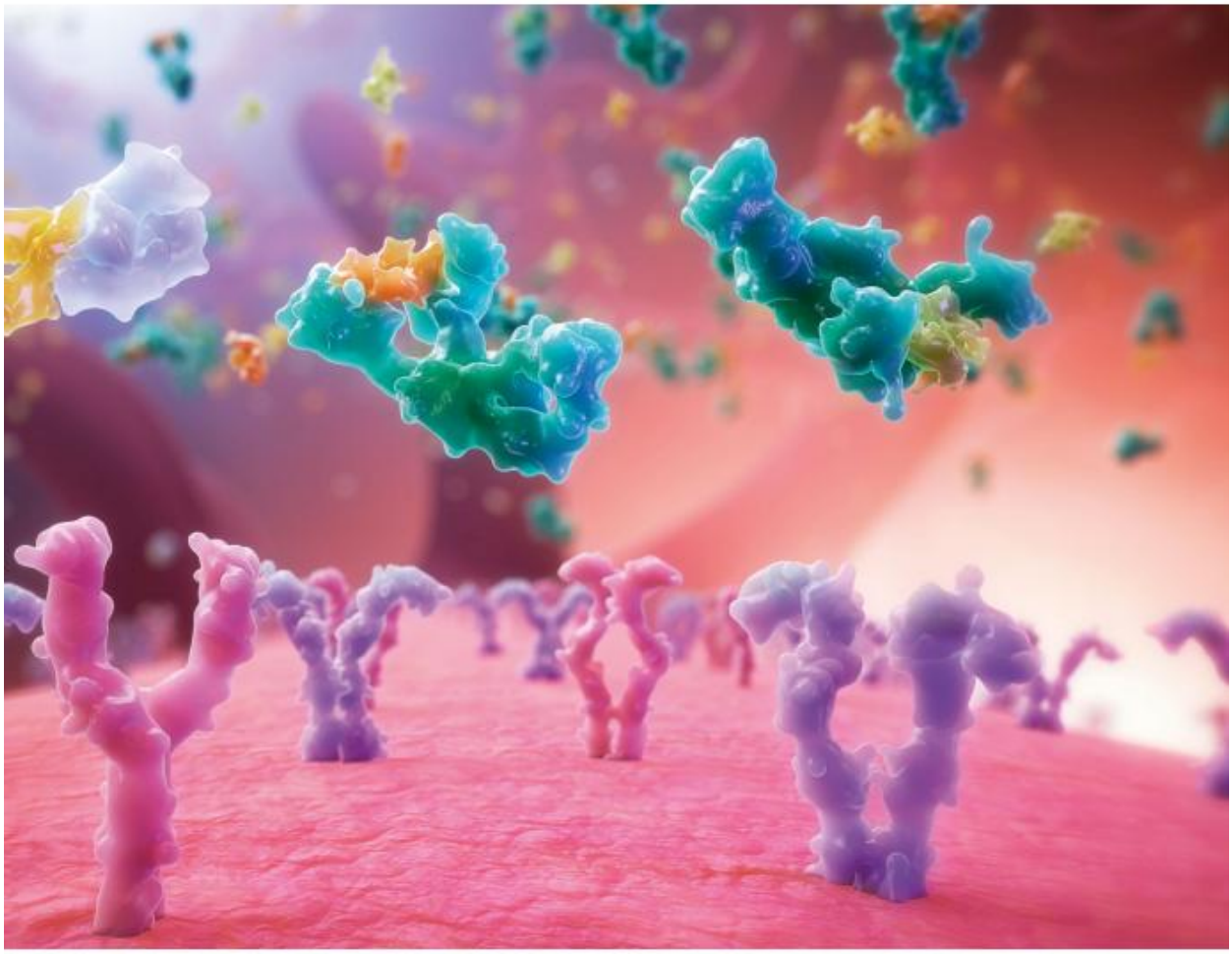
OPTHEA



HOPE IS ON THE HORIZON

2024 HALF-YEAR REPORT

Our cover

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

Contents

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, 2023. 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	Executive Director
Lawrence Gozlan	Non-Executive Director
Julia Haller	Non-Executive Director
Susan Orr	Non-Executive Director
Quinton Oswald	Non-Executive Director
Dan Spiegelman	Non-Executive Director
Anshul Thakral	Non-Executive Director

Operating & financial review

Financial performance

For the half year ended December 31, 2023, the Company's net loss before income tax is US$101,223,489 (December 31, 2022: US$79,143,755). 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 sozinibercept (OPT-302) for wet AMD and the continued manufacturing of sozinibercept in support of these trials:

- The total R&D expense was US$84,593,094 (December 31, 2022: US$61,433,565);
- The total administrative expenses was US$9,197,216 (December 31, 2022: US$17,491,830), last half year incurred higher advisory, consultants and legal fees associated with the development funding agreement ("DFA") with Ocelot SPV LP ("Ocelot" or "Investor") and equity financing deals of US$7 million, higher share-based payment expense of $1.1 million, additional bonus payments of $0.2 million, higher insurance costs, investor relations costs and other expenses of $0.7 million offset by lower salary costs of $0.7 million;
- The income tax benefit for the half year is US$5,038,058 (December 31, 2022: US$2,044,739); and
- Basic earnings per share were a loss of 16.23 cents (December 31, 2022: loss of 16.51 cents).

Financial position

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

- The cash position at December 31, 2023 was US$157,068,909 (June 30, 2023: US$89,188,713);
- The financial liability at December 31, 2023 was US$180,772,000 (June 30, 2023: US$85,660,000);
- A benefit of US$5,038,058, (December 31, 2022: US$2,044,739) was recognized in relation to the R&D Tax Incentive in the current period of US$5,286,646 netted against state taxes tax paid of US$248,587; and
- At December 31, 2023, the Net tangible asset backing per share was ($0.07) cents (June 30, 2023: ($0.01) cents).

Directors' Report (cont.)

Opthea: Corporate Overview

Opthea (ASX: OPT, Nasdaq: OPT) 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 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 sozinibercept (OPT-302), is being evaluated in two pivotal Phase 3 clinical trials (COAST, NCT04757636 and ShORe, NCT04757610) for use in combination with standard-of-care anti-VEGF-A monotherapies to improve overall efficacy and deliver superior vision gains compared to the standard-of-care anti-VEGF-A agents.

Lead drug sozinibercept

Opthea's lead candidate sozinibercept is a first-in-class vascular endothelial growth factor (VEGF)-C/D inhibitor being developed as a combination treatment with VEGF-A inhibitors for the treatment of wet age-related macular degeneration and other retinal diseases. Wet AMD is a progressive, chronic disease of the retina and in developed nations is the leading cause of visual impairment in people over the age of 50 years.

Sozinibercept has the potential to be the first new drug for wet AMD in more than 15 years to deliver superior visual gains when administered in combination with any anti-VEGF-A therapy for the treatment of wet AMD. It is being evaluated in two pivotal Phase 3 clinical trials investigating sozinibercept in combination with VEGF-A therapies, the current standard-of-care, for the treatment of wet AMD. This strategy is intended to maximize the commercial opportunity for sozinibercept by improving overall efficacy and achieving superior vision gains over those demonstrated by anti-VEGF-A treatment alone.

Wet AMD

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.

VEGF-inhibitors and wet AMD

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.

VEGF-A is a member of the VEGF family of proteins. It plays an important role in regulating the growth of abnormal new blood vessels and choroidal neovascularization in 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.

By combining administration of sozinibercept with a VEGF-A inhibitor, broader blockade of the VEGF receptor-1, 2 and 3 signaling 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, sozinibercept in combination with VEGF-A inhibitors, may result in more durable clinical responses.

Directors' Report (cont.)

VEGF-A inhibitors together generated worldwide revenues in excess of US$13 billion in 2023. The leading commercially available VEGF-A inhibitors for the treatment of wet AMD, ranibizumab (Lucentis®), aflibercept (Eylea®), together with bevacizumab (Avastin®), a VEGF-A inhibitor used off-label, account for approximately the vast majority 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®).

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.

The sozinibercept opportunity

Despite many patients experiencing gains or stabilization of vision, approximately 60% of patients with wet AMD exhibit a sub-optimal response to therapies that selectively target VEGF-A. As such, there remains a very large commercial opportunity for novel therapies that address the unmet medical need for patients who have further room for improvement in visual acuity, despite regular administration of currently available treatments.

Opthea's lead product candidate sozinibercept was designed to be superior to current therapies by providing improved clinical efficacy and more sustained and 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.

Opthea's Phase 2b clinical data supports the hypothesis that combining sozinibercept 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 sozinibercept and Lucentis (+14.2 letters, p-value=0.0107), compared with Lucentis monotherapy (+10.8 letters), representing an additional and statistically superior +3.4 letter gain in the total patient population as measured by best corrected visual acuity (BCVA). Furthermore, a mean gain of +5.7 letters (p-value=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 75% 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. The primary endpoint of our Phase 3 pivotal program targets minimally classic and occult patient populations where Opthea showed a +5.7 letter gain in BCVA score in the Phase 2b trial. Patient recruitment for the Phase 3 clinical trials is ongoing globally.

On February 14, 2024, Opthea announced that it has completed enrollment of all patients in the COAST Phase 3 pivotal clinical trial investigating sozinibercept in combination with aflibercept, an anti-VEGF-A therapy, for the treatment wet AMD. The sozinibercept clinical program includes two Phase 3 pivotal trials, COAST and ShORe. Enrollment in ShORe is expected to be completed in calendar Q2 2024. Opthea intends to report top-line results from these two trials by mid-2025.

Sozinibercept may offer superior visual outcomes for wet AMD patients, creating the first unique and significant efficacy advance in over 15 years. With positive Phase 2b data in wet AMD, Opthea believes sozinibercept is a promising drug candidate with large commercial potential as it advances through the final stage of clinical development, Phase 3 pivotal studies.

Directors' Report (cont.)

OPTHEA: WORKING TO ADDRESS THE MAJOR UNMET NEED IN WET AMD PATIENTS TO IMPROVE VISUAL FUNCTION OUTCOMES WITH SOZINIBERCEPT COMBINATION THERAPY OVER AND ABOVE ANTI-VEGF-A MONOTHERAPY POTENTIALLY CREATING SUPERIOR OUTCOMES AND TARGETING A LARGE MARKET OPPORTUNITY

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 the 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 sozinibercept, 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.

In 2023, Lucentis, Vybasmo, and Eylea/Eylea HD generated combined revenues in excess of US$13 billion (all indications), 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.

SOZINIBERCEPT: FIRST AND ONLY NOVEL INVESTIGATIONAL "TRAP" MOLECULE TARGETING VEGF-C AND VEGF-D FOR TREATMENT OF WET AMD TO PROVIDE POTENTIALLY SUPERIOR TREATMENT REGIME

Opthea is developing sozinibercept as a complementary treatment to be used in conjunction with VEGF-A inhibitors for the treatment of wet AMD and other retinal diseases.

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. Sozinibercept 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, sozinibercept is the most advanced product in clinical development with demonstrated potential to improve patient visual outcomes and tap into an expanding global branded retina market opportunity of potentially greater than US$13 billion per annum.

The primary endpoint of Opthea's global Phase 3 pivotal trial program is superiority in Best Corrected Visual Acuity (BCVA) over monotherapy in combination with sozinibercept. In our Phase 2b, Opthea demonstrated a mean gain of +5.7 letters (p-value=0.0002) 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 75% of patients enrolled in the Phase 2b trial and the primary endpoint of the Phase 3 pivotal trial program.

Sozinibercept could be the first product in wet AMD to demonstrate superior gains in vision in over 15 years.

Directors' Report (cont.)

Operational update

For the six months ended December 31, 2023, Opthea has made significant progress in obtaining additional funding for the Phase 3 studies and has made strides resulting in increased patient enrollment.

In August 2023, Opthea successfully completed a placement and Institutional entitlement offer of A$90 million fully underwritten pro-rated accelerated non-renounceable entitlement.

Previously under the DFA, Investor had committed to provide Opthea US$120 million in funding which may be increased up to US$170 million at its option. In December 2023, Opthea received the final US$35 million tranche from the original DFA bringing the funding to US$120 million. An additional US$50 million in funding was received from a co-investor under an amended DFA, with similar terms, also in December 2023, bringing the total DFA funding to US$170 million. Under the DFA, Opthea is required to use commercially reasonable efforts to develop sozinibercept for the treatment of wet AMD in accordance with the DFA, including pursuant to certain development timelines set forth therein.

At December 31, 2023, Opthea had cash and cash equivalents of US$157 million, which includes the proceeds from the equity financing, together with remaining tranches of the non-dilutive funding under the DFA.

For the six months ended December 31, 2023, the main focus for Opthea was activation of clinical trial sites worldwide and patient enrollment. The trials are global, multicenter, randomized, sham-controlled aiming at demonstrating superiority in efficacy in combination versus standard of care. These global Phase 3 clinical trials are referred to as "ShORe: Study of sozinibercept (OPT-302) in combination with Ranibizumab" and "COAST: Combination sozinibercept with Aflibercept Study", in each trial, patients are randomized to one of three arms. In the ShORe study patients receive sozinibercept plus Lucentis (on one of two dosing schedules) or Lucentis plus sham injection ("sham"). In the COAST study patients receive sozinibercept plus Eylea (on one of two dosing schedules) or Eylea plus sham. Each trial is designed to enroll approximately 912-990 treatment naïve patients and will investigate the mean change in best corrected visual acuity from baseline to week 52 for sozinibercept in combination with an approved VEGF-A inhibitor (Lucentis or Eylea) administered on an every four-week, and on an every eight-week, dosing cycle, after the first three loading doses 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 sozinibercept combination therapy for the treatment of wet AMD, while evaluating the administration of sozinibercept in combination with approved VEGF-A inhibitors over a longer treatment period and in a greater number of patients.

As of December 31, 2023, there were 198 activated clinical trial sites in ShORe in 22 countries. In COAST, there were 219 clinical trial sites in 30 countries.

Over the next twelve months, Opthea will continue to work with our global Clinical Research Organization ("CRO") to consolidate engagement with trial sites and investigators and finalize eligible patients for enrollment into the ShORe 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, competition for patients and clinical sites from other drug candidates, 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, sozinibercept, 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 in the first half of calendar-year 2024, 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, which we expect in mid-calendar 2025. If top-line results at the completion of the primary efficacy phase are favorable, Opthea intends to file for marketing approval for sozinibercept for the treatment of wet AMD in the US, European Union and other territories.

Directors' Report (cont.)

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 2023, Dr Frederic Guerard joined as Chief Executive Office and Peter Lang joined Opthea as Chief Financial Officer, based in the US. Both are two well-respected healthcare executives with a record of building and growing organizations, guiding R&D pipelines, leading commercial operations, and managing finances while providing strategic direction and successfully steering companies through critical corporate, clinical and commercial growth inflection points.

During the previous year, Opthea continued to undertake activities 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 sozinibercept delivered by Dr. Baldwin, at the American Academy of Ophthalmology Meeting in Chicago, Illinois, and a presentation on sozinibercept 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 sozinibercept, 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 the Philippines and pending divisional or continuation applications in the US, Europe and Malaysia. The patents have claims covering the composition of matter of sozinibercept 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 sozinibercept. 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. Upon approval in the US, we expect to be granted twelve years of market exclusivity given to novel biologics.

Opthea owns another granted patent relating to soluble VEGFR-3 molecules which includes composition of matter claims to soluble VEGFR-3 molecules (such as sozinibercept) 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 Opthea has continued to raise the profile of sozinibercept and the Phase 3 pivotal 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 2023, Opthea announced, and subsequently closed in September, a A$90 million (US$58 million) rights issue and placement equity offering. In November 2023, Opthea attended the American Academy of Ophthalmology Conference held in San Francisco. Also, in November 2023, Opthea presented at the Jefferies Healthcare Conference in London. In December 2023, Opthea met with several Australian investors and participated in a call sponsored by MST Securities to its investor network.

Subsequent events

On February 14, 2024, Opthea announced completion of enrollment for the COAST Phase 3 clinical trial.

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.

Directors' Report (cont.)

Future developments

Opthea continues to advance the clinical development of sozinibercept 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 clinical trials;
- Continue to manufacture current Good Manufacturing Practice (cGMP), clinical grade sozinibercept for use in Phase 3 clinical trials; and
- Progress manufacturing activities to support commercial supply of sozinibercept.

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 sozinibercept and the resultant value of Opthea;
- Continue preparation for sozinibercept regarding potential regulatory filing and commercialization; and
- Prepare for various opportunities to advance further development and commercialization of sozinibercept through engagement with pharmaceutical/biotechnology companies.

On behalf of the Directors

Jeremy Levin
Chairman

February 29, 2024

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, 2023 as filed with the Securities and Exchange Commission on September 29, 2023, including our condensed consolidated 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, 2023 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, 2023 or the following uncertainties to imply that such risks have not already materialized.

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$157 million of cash at December 31, 2023. Opthea believes that it will be able to fund its operating and research and development expenses through at least the third calendar quarter of 2024. As such, Opthea expects to raise additional external funding, including through equity financing, prior to its reporting of top-line data for its Phase 3 clinical trials. 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 the timing of regulatory submissions, the performance and cost efficiency of contract research organizations ("CROs") and contract manufacturers, and the continuing impacts of 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 sozinibercept 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 sozinibercept for the treatment of wet AMD, and Opthea will require additional funding to reach commercialization of sozinibercept in any indication, including wet AMD. In addition, Opthea will 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. If Opthea experiences further delays in its Phase 3 clinical trials, Opthea may need to raise additional external funding, including potentially dilutive equity financing.

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. In December 2023, Opthea received the last $35 million tranche under the DFA as well as an additional $50 million as part of an amended DFA from a new co-investor. If Opthea raises additional capital, this may cause dilution to holders of the Company's ordinary shares and American Depositary Shares. Opthea also expects to raise additional capital, including through potentially dilutive equity financings, to further support its clinical trials for sozinibercept.

Auditor's Independence Declaration

Deloitte.

Deloitte Touche Tohmatsu
ABN 74 490 121 060

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Australia

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29 February 2024

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

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 ("Opthea").

As lead audit partner for the review of the half year financial report of Opthea Limited for the half year ended 31 December 2023, 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 faithfully

DELOITTE TOUCHE TOHMATSU

Chetan Vaghela
Partner
Chartered Accountants

Condensed Consolidated Statement of Profit or Loss and Other Comprehensive Income

For the half year ended December 31, 2023

	Note	December 31 2023 US$	2022 US$
Revenue	4	60,798	52,107
Other income		141,436	144,961
Research and development expenses	5	(84,593,094)	(61,433,565)
Patent and intellectual property expenses		(148,687)	(81,621)
Administrative expenses	6	(9,197,216)	(17,491,830)
Interest expense on DFA*	7	(10,499,284)	(3,480,696)
Finance income – interest income		1,798,425	1,107,859
Fair value adjustment gain on DFA*	8	387,284	–
Net foreign exchange gain		826,849	2,039,030
Loss before income tax		**(101,223,489)**	**(79,143,755)**
Income tax benefit	9	5,038,058	2,044,739
Loss for period		**(96,185,431)**	**(77,099,014)**
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		**(96,185,431)**	**(77,099,014)**
Earnings per share for loss attributable for the ordinary equity holders of the parent:			
Basic and diluted loss per share (cents)		(16.23)	(16.51)

* Development Funding Agreement ("DFA").

Notes to the condensed consolidated financial statements are included on pages 16 to 28.

Condensed Consolidated Statement of Financial Position

As at December 31, 2023

	Note	December 31 2023 US$	June 30 2023 US$
Current Assets			
Cash and cash equivalents	10	157,068,909	89,188,713
Current tax receivable		5,286,646	5,926,350
Receivables		509,920	636,564
Prepayments	11	3,470,126	2,634,671
Total current assets		**166,335,601**	**98,386,298**
Non-current assets			
Equipment		28,263	33,035
Right-of-use assets	12	126,338	168,451
Prepayments		10,565	53,535
Total non-current assets		**165,166**	**255,021**
Total assets		**166,500,767**	**98,641,319**
Current liabilities			
Payables		31,703,998	17,891,854
Lease liabilities	13	87,722	97,485
Provisions		798,483	753,300
Total current liabilities		**32,590,203**	**18,742,639**
Non-current liabilities			
Lease liabilities	13	42,113	84,226
Financial liabilities	14	180,772,000	85,660,000
Provisions		10,175	7,631
Total non-current liabilities		**180,824,288**	**85,751,857**
Total liabilities		**213,414,491**	**104,494,497**
Net liabilities		**46,913,724**	**5,853,178**
Equity			
Contributed equity	15	374,320,334	320,883,552
Accumulated losses		(455,647,868)	(359,462,438)
Reserves	16	34,413,810	32,725,708
Total equity		**(46,913,724)**	**(5,853,178)**

Notes to the condensed consolidated financial statements are included on pages 16 to 28.

Condensed Consolidated Statement of Changes in Equity

For the half year ended December 31, 2023

	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, 2023	**320,883,552**	**11,551,134**	**1,085,411**	**20,089,163**	**(359,462,438)**	**(5,853,178)**
Loss for the period	–	–	–	–	(96,185,431)	(96,185,431)
Total comprehensive income and expense for the period	–	–	–	–	(96,185,431)	(96,185,431)
Issue of ordinary shares (net of costs US$4,763,200)	53,435,888	–	–	–	–	53,435,888
Recognition of share-based payment	–	1,688,102	–	–	–	1,688,102
Issue of ordinary shares on exercise of options from equity financing	894	–	–	–	–	894
Balance at December 31, 2023	**374,320,334**	**13,239,236**	**1,085,411**	**20,089,163**	**(455,647,868)**	**(46,913,724)**
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 the exercise of options	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**

Notes to the condensed consolidated financial statements are included on pages 16 to 28.

Condensed Consolidated Statement of Cash Flows

For the half year ended December 31, 2023

	December 31	
	2023 US$	2022 US$
Cash flows from operating activities		
Interest received	1,795,464	860,604
Royalty and license income received	60,798	52,107
Grant and other income received	80,835	141,301
Payment of lease interest	(2,661)	(2,661)
Payments to suppliers, employees and for research and development and intellectual property costs	(77,220,947)	(70,337,710)
Research and development tax incentive scheme credit received	5,926,350	-
Net cash flows used in operating activities	**(69,360,161)**	**(69,286,359)**
Cash flows from investing activities		
Purchase of equipment	(4,256)	(7,019)
Net cash flows used in investing activities	**(4,256)**	**(7,019)**
Cash flows from financing activities		
Payment of lease liabilities	(51,877)	(42,025)
Net proceeds on issue of shares	53,435,888	81,815,357
Net proceeds from DFA	85,000,000	84,500,000
Cash received for ordinary shares issued on exercise of options	894	921,731
Net cash flows provided by financing activities	**138,384,905**	**167,195,063**
Net increase in cash and cash equivalents	69,020,488	97,901,685
Effect of foreign exchange rate changes	(1,140,292)	(760,549)
Cash and cash equivalents at beginning of the period	89,188,713	44,631,293
Cash and cash equivalents at end of the period	**157,068,909**	**141,772,429**

Notes to the condensed consolidated financial statements are included on pages 16 to 28.

Notes to the Condensed Consolidated Financial Statements

For the half year ended December 31, 2023

1. Corporate Information

The condensed consolidated financial report of Opthea Limited (the "Group"), for the half year ended December 31, 2023 were authorized for issue in accordance with a resolution of the directors on February 29, 2024.

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, 2023.

There were no changes in accounting policy during the half year ended December 31, 2023, nor did the introduction of new accounting standard lead to any changes in measurement or disclosure in these condensed consolidated 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 condensed consolidated financial statements are provided in the annual financial report.

Going concern

The condensed consolidated financial statements have been prepared on a going concern basis, which contemplates continuity of normal activities and realization of assets and settlement of liabilities in the normal course of business.

For the half year ended December 31, 2023, the Group incurred a loss after income tax of $96,185,431 (2022: $77,099,014) and had net cash outflows from operating activities of $69,360,161 (2022: $69,286,359). As at December 31, 2023, the Group had cash and cash equivalents of $157,068,909 (June 2023: $89,188,713), net current assets of $133,745,398 (June 2023: $79,643,659) and was in a net liability position of $46,913,724 (June 2023: net liability $5,853,178).

While the Group expects that the cash on hand at December 31, 2023 of $157 million will be able to fund its operations through the third calendar quarter of 2024, such proceeds will not be sufficient to fully fund all anticipated costs of the Phase 3 clinical trials to top-line data, expected in mid-calendar year 2025. The Group will need to raise significant funds to complete the efficacy and safety phase of both studies and to report top-line data (primary end point). As the Group is still in the research and development phase, the ability of the Group to continue its development activities as a going concern is dependent on it deriving sufficient cash from investors.

The Group does not have any committed external source of funds and expects to finance future cash needs through public or private equity or potential collaborations within select regions such as the US, EU, Australia, or rest of world markets, to leverage greater market exposure and to commercialize sozinibercept for wet AMD.

Opthea has a US$350 million shelf of American Depositary Shares ("ADS") on file with the Securities and Exchange Commission ("SEC") which it can draw upon in the US market until its expiry in February 2025. Under this shelf, Opthea may offer and sell up to US$75 million of its ordinary shares in the form of ADSs through Jeffries, with each ADS representing eight ordinary shares (the "At the Market Program" or "ATM Program"). Opthea has not sold any ordinary shares under the ATM Program and the ability to raise capital under this program is subject to market conditions and is not guaranteed.

Under a going concern notification to the Amended Development Funding Agreement ("DFA") investors, the DFA investors have the option, but not the obligation, to contribute additional funds under the existing DFA terms if the Group cannot sufficiently raise capital in a timely manner.

The Directors and management have considered the cash flow forecasts including the funding requirements of the business. They have also considered the Group's key risks and uncertainties affecting the likely development of the business, as well as the progress of the clinical trials. On February 14, 2024, the Group announced that it had fully enrolled the COAST Phase 3 trial and the ShORe Phase 3 trial is expected to close enrollment in second calendar quarter of 2024. The completion of the enrollments of these trials is a key milestone in the Company's plans to commercialize sozinibercept for wet AMD.

Notes to the Condensed Consolidated Financial Statements (cont.)

While the Group has an ability to manage the timing of expected future cash outflows, any such delays may have an impact on the progress the clinical trials and timing of regulatory approval. The Group has a history of successfully raising capital to fund its ongoing operations, including most recently a A$90 million (US$58 million) private placement and rights equity offering in August of 2023 and securing the US$50 million option under the Amended DFA in December 2023. Based on this assessment, the Directors and management believe that the Group has, between its existing funds and the funds it is reasonably likely able to raise, adequate funding to continue normal activities and realize its assets and settle its liabilities in the normal course of business. Accordingly, the directors have prepared the condensed consolidated financial statements on the going concern basis.

There is no guarantee that sufficient funds will be able to be raised to finance operations for twelve months from the issuance of these condensed consolidated financial statements. Therefore, a material uncertainty exists which may cast significant doubt as to whether the Group will continue as a going concern and, therefore, that it may be unable to realize its assets and discharge its liabilities in the normal course of business.

The condensed consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or to the amounts and classification of liabilities that might be necessary should the Group not continue as a going concern.

3. 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 condensed consolidated financial statements are consistent with these adopted and disclosed in the Company's 2023 annual financial report for the financial year ended June 30, 2023, except as outlined below, the accounting policies and methods of computation. The accounting policies are consistent with Australian Accounting Standards and with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Functional and Presentation currency

The Group's functional and presentation currency in all periods presented was US Dollars.

Change in presentation of share-based payments expense

The Group changed its presentation of share-based payments expense by reclassifying the expense into Administrative expense – to better reflect the nature of the administrative operating expense. 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.

Notes to the Condensed Consolidated Financial Statements (cont.)

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. No upfront license fees were received in either period; 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, 2023, 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, sozinibercept. 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. At half year the estimate is based on the eligible Australian and Overseas expenditure recognized in the period. 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*.

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.

Notes to the Condensed Consolidated Financial Statements (cont.)

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 twelve 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. The Group's Financial Liability recognized the obligations under the Development Funding Agreement of the sales milestones and the expected fixed and variable contractual success fee payments.

Amortized cost and effective interest method

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

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

Revaluation

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

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 and International Financial Reporting Standards as issued by the International Accounting Standards Board.

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 condensed consolidated financial statements.

The Group's 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 sozinibercept 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, 2023, of US$60,798 (December 31, 2022: US$52,107) was generated from customers based in the United States. The Group does not have any major customers. All equipment is located in Australia and United States.

Notes to the Condensed Consolidated Financial Statements (cont.)

5. Research and development expenses

	2023 US$	2022 US$
Research project costs[1]	84,593,094	61,433,565
Total research and development expense	**84,593,094**	**61,433,565**

1. The research project costs relate to the research programs in respect to the treatment of eye disease by sozinibercept.

6. Administration expenses

	2023 US$	2022 US$
Administrative expenses		
Employee benefits expenses:		
Salaries and fees	3,661,910	2,915,181
Cash bonuses	511,950	744,117
Superannuation	140,674	153,726
Share-based payments expense	1,688,102	2,852,378
Total employee benefits expense	**6,002,636**	**6,665,402**
Other expenses:		
Insurance	1,060,076	1,472,993
Investor relations costs	149,049	268,154
Audit and accounting	149,010	128,431
Travel expenses	307,315	227,576
Payroll tax	147,616	136,429
Legal fees	655,530	782,927
Advisory fees[1]	184	5,996,133
Consultancy costs	133,969	1,031,944
Other expenses	540,688	732,423
Total other expenses	**3,143,437**	**10,777,010**
Depreciation of:		
Equipment and furniture	9,030	7,305
Right-of-use assets	42,113	42,113
Total depreciation expense	**51,143**	**49,418**
Total administrative expenses	**9,197,216**	**17,491,830**

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

Notes to the Condensed Consolidated Financial Statements (cont.)

7. Interest expense on DFA

	2023 US$	2022 US$
Interest expense on DFA	10,499,284	3,480,696
	10,499,284	**3,480,696**

The interest expense on DFA is non-cash interest at the imputed rate of approximately 23%.

8. Fair value adjustment gain on DFA

	2023 US$	2022 US$
Fair value adjustment gain on DFA	387,284	-
	387,284	**-**

There are several factors that could affect the estimated timing of regulatory approval and attainment of sales milestones, some of which are not entirely within the Group's control. Therefore, at each reporting date, the Group reassesses the estimated timing of regulatory approval, commercial launch and attainment of sales milestones and the expected fixed and variable contractual success fee payments due therefrom. If the timing and/or amount of such expected payments is materially different from the estimates used on the initial recognition date, the Group will adjust the accretion of the development financing liability using the previously determined imputed interest rate. If the dates are delayed from those used at December 31, 2023, it is expected that a fair values adjustment will result in another non-cash gain. If the timelines for approval and launch are accelerated the Group would anticipate a fair value adjustment resulting in a non-cash charge to be recognized on the Profit or Loss statement.

At December 31, 2023, the Group performed a fair value adjustment of the carrying amount of the Financial Liability recognized under the Development Funding Agreement. The fair value adjustment resulted in a non-cash gain on revaluation of $0.4 million. This change is recorded on the Profit or Loss statement as an unrealized fair value adjustment gain on the DFA. The Group will continue to accrete non-cash interest at the imputed rate of approximately 23%. Refer to Note 7.

9. 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:

	2023 US$	2022 US$
Accounting loss before tax	(101,223,489)	(79,143,754)
At the parent entity's statutory income tax rate of 30%	30,367,047	23,743,126
Research and development tax incentive on eligible expenses	5,286,646	2,044,739
Non-deductible R&D expenditure	(3,645,962)	(1,410,165)
Other non-deductible expenses – share-based payment expense	(506,431)	(855,713)
Amount of temporary differences and carried forward tax losses not recognized	(26,463,242)	(21,477,248)
Income tax benefit reported in the Statement of Profit or Loss and Other Comprehensive Income	**5,038,058**	**2,044,739**

Notes to the Condensed Consolidated Financial Statements (cont.)

10. Cash and cash equivalents

	December 31 2023 US$	June 30 2023 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	90,433,753	12,067,158
Short-term deposits	66,635,156	77,121,555
	157,068,909	**89,188,713**

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 92 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 4.75% (2022 half year: 3.87%). The only restriction on term deposits is the loss of interest earnt if term is broken.

11. Prepayments

	December 31 2023 US$	June 30 2023 US$
R&D Contract Research Organization	1,893,099	1,693,964
Insurance	1,382,473	717,064
Other prepayments	194,554	223,643
	3,470,126	**2,634,671**

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, recruit patients 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 twelve 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 directors' and officers' insurance. The non-current portion of the prepayments are recorded as non-current assets which relates specifically to Phase 3 clinical trial insurance.

Notes to the Condensed Consolidated Financial Statements (cont.)

12. Right-of-use assets

	December 31 2023 US$	June 30 2023 US$
Right-of-use asset cost		
Opening balance	534,231	281,554
Additions	–	252,667
Exchange on translation	–	–
	534,231	**534,231**
Accumulated depreciation		
Opening balance	(365,780)	(281,554)
Charge for the period	(42,113)	(84,226)
Exchange on translation	–	–
	(407,892)	**(365,780)**
Net carrying amount	**126,339**	**168,451**

The Group has a three-year lease contract for its head office premises in Melbourne, Australia which commenced on July 15, 2022.

The maturity analysis of lease liabilities is presented in Note 13.

13. Lease liabilities

	December 31 2023 US$	June 30 2023 US$
Carrying amount at July 1	**181,711**	**–**
New Lease	–	252,677
Payments	(51,876)	(70,966)
Carrying amount at December 31/June 30	**129,835**	**181,711**
Maturity analysis:		
Year 1	90,383	102,806
Year 2	42,113	84,226
	132,496	187,032
Less: unearned interest	(2,661)	(5,321)
	129,835	**181,711**
Analyzed into:		
Current portion	87,722	97,485
Non-current portion	42,113	84,226
	129,835	**181,711**

Notes to the Condensed Consolidated Financial Statements (cont.)

14. Financial liabilities

	December 31 2023 US$	June 30 2023 US$
Carrying amount at July 1	**85,660,000**	–
Funding at fair value	85,000,000	84,500,000
Amortized interest	10,499,284	13,462,160
Fair value gain on DFA	(387,284)	(12,302,160)
Carrying amount at December 31/June 30	**180,772,000**	**85,660,000**

Pursuant to the DFA and amended DFA, Ocelot SPV LP, an affiliate of Carlyle and Abingworth, in collaboration with Carlyle's and Abingworth's development company Launch Therapeutics, and together with a co-investor (together, the "DFA Investors") have committed to provide Opthea US$170 million in funding, of which US$85 million was paid in December 2023. Opthea is required to use commercially reasonable efforts to develop sozinibercept for the treatment of wet AMD in accordance with the DFA and amended DFA, including pursuant to certain development timelines set forth therein. The amended DFA resulted in a co-investor contributing funding of $50 million directly to the Company in December 2023 on the same terms and conditions as the existing agreement. The Company exercised significant judgement in accounting for the amended DFA, including consideration of whether the amended DFA resulted in a modification of the original loan. The Company concluded that the amended DFA agreement forms part of the existing agreement as the US$50 million is contemplated in the existing agreement on the same return and repayment profile, and there have been no substantive changes in the original terms and conditions of the loan.

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

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

There are several factors that could affect the estimated timing of regulatory approval and attainment of sales milestones, some of which are not entirely within the Group's control. Therefore, at each reporting date, the Group reassesses the estimated timing of regulatory approval and attainment of sales milestones and the expected contractual success fee payments due therefrom. If the timing and/or amount of such expected payments is materially different than original estimates, the Group will prospectively adjust the accretion of the development financing liability and the imputed interest rate. Refer to Note 7.

As of December 31, 2023, the development financing liability was classified as a long-term liability, as the Group expects the related repayments to take place between 2027 and 2032 for purposes of the model used to calculate its carrying value. The imputed interest rate on the unamortized portion of the development financing liability was approximately 23%.

Notes to the Condensed Consolidated Financial Statements (cont.)

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

The DFA contains terms that require compliance by the Company to maintain a minimum cash balance and to provide a notice to Ocelot in the event it anticipates that it does not have sufficient cash to fund its operations for the next six months. The Group remains in compliance with the minimum cash balance requirements of the DFA.

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

15. Contributed equity

	December 31 2023 US$	June 30 2023 US$
(a) Ordinary Shares		
Issued and fully paid at December 31/June 30	374,320,334	320,883,552
Movement in ordinary shares:		
Opening balance	320,883,552	235,277,217
Issue of shares on exercise of options granted under the Long Term Incentive Plan (LTIP)	–	3,790,978
Issue of shares on exercise of options from Placement and Institutional offer	894	–
Issue of shares from Placement and Institutional offer	53,435,888	81,815,357
	374,320,334	**320,883,552**

Ordinary shares on issue:	No:	No:
Opening balance	467,159,434	352,152,542
Issue of shares on exercise of options granted under the Long Term Incentive Plan (LTIP)	–	2,387,826
Issue of shares on exercise of options from Placement and Institutional offer	1,743	–
Issue of shares from Placement and Institutional offer	195,647,457	112,619,066
	662,808,634	**467,159,434**

Issued capital of ordinary shares at December 31, 2023 amounted to US$374,320,334 (662,808,634 fully paid ordinary shares) net of share issue costs and tax. The Company issued 195,647,457 ordinary shares, at a price per ordinary share of A$0.46, net of issue costs in respect of placement and institutional offer in August and September 2023 as well as listing 97,823,728 options expiring August 31, 2025 with an exercise price of $0.80 cents per ordinary share.

Notes to the Condensed Consolidated Financial Statements (cont.)

16. Reserves

	December 31 2023 US$	June 30 2023 US$
Fair value of investments reserve[1]	1,085,411	1,085,411
Share-based payments reserve[2]	13,239,236	11,551,134
Foreign currency translation reserve[3]	20,089,163	20,089,163
Total reserves	**34,413,810**	**32,725,708**
1. Movement in fair value of investments reserve:		
Opening balance	1,085,411	1,085,411
Closing balance	**1,085,411**	**1,085,411**
2. Movement in share-based payments reserve:		
Opening balance	11,551,134	8,466,706
Share-based payments expense	1,688,102	5,834,686
Exercise of options	–	(2,750,258)
Closing balance	**13,239,236**	**11,551,134**
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$ upon change of functional currency.

17. Related party disclosures

(a) Subsidiaries

	Parent entity % equity interest	
	December 31 2023	December 31 2022
Vegenics Pty Ltd[1]	100	100
Opthea US Inc[2]	100	100

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

Notes to the Condensed Consolidated Financial Statements (cont.)

(b) Transactions with related parties

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

- Launch, Ocelot and Carlyle became related parties, with the appointment of Anshul Thakral (who is the CEO of Launch and Operation Executive of Carlyle) on June 7, 2023, as a Director of Opthea; and
- Consultancy agreement with Non-Executive Director Lawrence Gozlan for services provided on financing activities.

Trading transactions

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

	Consolidated Purchase of Service	
	2023 US$	2022 US$
Ocelot and co-investor	–	–
Launch	1,350,000	–
Lawrence Gozlan	125,000	–
	1,450,000	**–**

Purchase of service assisting Opthea with the management and oversight of trials under the Service Agreement with Launch Tx and Consultancy agreement with Mr Gozlan.

	Consolidated Amount owed to related parties	
	December 31 2023 US$	June 30 2023 US$
Ocelot and co-investor	180,772,000	85,660,000
Launch	–	–
Lawrence Gozlan	–	–
	180,772,000	**85,660,000**

Amounts owed to Ocelot relate to the Development Funding agreement and carry an effective interest rate of approximately 23% (refer to Note 7).

Notes to the Condensed Consolidated Financial Statements (cont.)

18. 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 sozinibercept. Expenditure commitments relating to these and intellectual property license agreements are payable as follows:

	December 31 2023 US$	June 30 2023 US$
Within one year	21,534,759	12,632,801
After one year but not more than five years	7,199,306	12,302,260
After more than five years	–	30,000
	28,734,065	**24,965,061**

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

(ii) Commercial commitments

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

	December 31 2023 US$	June 30 2023 US$
Within one year	16,500	47,415
After one year but not more than five years	–	–
After more than five years	–	–
	16,500	**47,415**

19. Events subsequent to reporting date

On February 14, 2024, Opthea announced completion of enrollment for the COAST Phase 3 clinical trial.

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

Forward-looking statements, including projections, guidance on the future financial position of the Company is provided as a general guide only and should not be relied upon as an indication or guarantee of future performance. They involve known and unknown risks and uncertainties and other factors, many of which are beyond the control of Opthea and its directors and management and may involve significant elements of subjective judgment and assumptions as to future events that may or may not be correct. These statements may be affected by a range of variables which could cause actual results or trends to differ materially, including, but not limited to, the risks described more fully in the section titled "Risk Factors" included at the end of this report, in Opthea's Annual Report on Form 20-F filed with the SEC on September 28, 2023 under "Key Risks", including risks associated with: future capital requirements, the development, testing, production, marketing and sale of drug treatments, regulatory risk and potential loss of regulatory approvals, ongoing clinical studies to demonstrate sozinibercept safety, tolerability and therapeutic efficacy, additional analysis of data from Opthea's Phase 3 clinical trials once unmasked, timing of completion of Phase 3 clinical trial patient enrollment and CRO and labor costs, intellectual property protections, and other factors that are of a general nature which may affect the future operating and financial performance of the Company. No representation, warranty, or assurance (express or implied) is given or made in relation to any forward-looking statement by any person (including the Company and Opthea Related persons). In particular, no representation, warranty or assurance (express or implied) is given that the occurrence of the events expressed or implied in any forward-looking statements in this report will actually occur. Actual results, performance or achievement may vary materially from any projections and forward-looking statements and the assumptions on which those statements are based. The forward-looking statements in this report speak only as of the date of this report. Subject to any continuing obligations under applicable law or any relevant ASX listing rules, the Company and Opthea related persons disclaim any obligation or undertaking to provide any updates or revisions to any forward-looking statements in this report to reflect any change in expectations in relation to any forward-looking statements or any change in events, conditions, or circumstances on which any such statement is based. Nothing in this report will create an implication that there has been no change in the affairs of Opthea since the date of this report.

Directors' Declaration

The Directors declare that:

(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 29, 2024

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

Deloitte.

Deloitte Touche Tohmatsu
ABN 74 490 121 060

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Melbourne VIC 3000
Australia

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

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 2023, 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 to the financial statements, including material accounting policy information and other explanatory information, and the directors' declaration as set out on page 30.

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the accompanying half-year financial report of the Group does not comply with the *Corporations Act 2001*, including:

- Giving a true and fair view of the Group's financial position as at 31 December 2023 and of 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*.

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 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 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.

Material Uncertainty related to Going Concern

We draw attention to Note 2 of the condensed consolidated financial statements which indicates that the Group incurred a net loss of $96.2 million, had a net cash outflow from operating activities of $69.4 million during the half-year ended 31 December 2023, and, as of that date, the Group had an equity deficit of $46.9 million.

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

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.

Independent Auditor's Review Report to the Members of Opthea Limited (cont.)

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 2023 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.

DELOITTE TOUCHE TOHMATSU

Chetan Vaghela
Partner
Chartered Accountants
Melbourne, 29 February 2024

Corporate Information

Company

Opthea Limited
ABN 32 006 340 567

Directors

Jeremy Levin
Non-Executive Director and Chairman

Megan Baldwin
Executive Director

Lawrence Gozlan
Non-Executive Director

Julia Haller
Non-Executive Director

Susan Orr
Non-Executive Director

Quinton Oswald
Non-Executive Director

Anshul Thakral
Non-Executive Director

Daniel Spiegelman
Non-Executive Director

Company Secretary

Karen Adams
BBus, CPA GAICD, FGIA FCG

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Auditors

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Solicitors

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Palo Alto, CA, USA, 94304

Share Register

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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).

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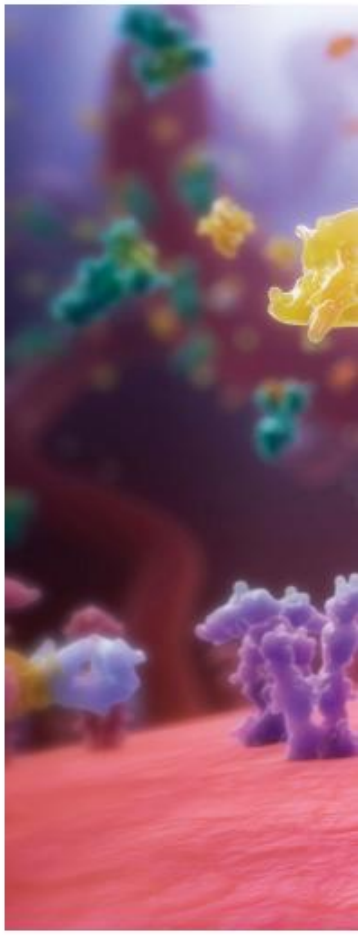

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