Opthea Reports Half Year Results and Business Updates

Cash and cash equivalents of $131.9M as of December 31, 2024

Cash runway extends through anticipated topline data readouts of COAST (early 2Q CY25) and ShORe (mid-CY25)

Melbourne, Australia, and Princeton, NJ, US, February 28, 2025 -- Opthea Limited (ASX/NASDAQ: OPT, "Opthea", the "Company"), a clinical-stage biopharmaceutical company developing novel therapies to treat highly prevalent and progressive retinal diseases, including wet age-related macular degeneration (wet AMD), today announced financial results for the six months ended December 31, 2024, and highlighted recent corporate and clinical updates.

"Opthea is making significant progress on its mission to deliver superior vision to patients with wet AMD enabling them to live fuller and healthier lives," said Frederic Guerard, PharmD, Chief Executive Officer of Opthea. "Sozinibercept has the potential to be the first product in nearly 20 years to demonstrate superior visual outcomes in combination with standard of care therapy, and we look forward to the anticipated topline data readouts of our two Phase 3 clinical trials in early Q2 and mid-calendar year 2025."

Tom Reilly, Chief Financial Officer of Opthea, added: "Looking ahead, we expect our cash and cash equivalents to fund the Company through the anticipated topline data readouts of the Phase 3 COAST and ShORe trials. In addition, we continue to progress our manufacturing (CMC) activities as we prepare our Biologics License Application (BLA) for FDA submission, and ready the organization to potentially launch sozinibercept in wet AMD."

Anticipated Milestones

- Phase 3 topline results from COAST, expected in early Q2 CY2025
- Phase 3 topline results from ShORe, expected in mid-CY2025
- BLA submission in 1H CY2026

Corporate Highlights

- In February 2025, completed Drug Product PPQ campaign and week 52 last patient last visit in COAST Phase 3 trial evaluating sozinibercept in combination with aflibercept.
- In January 2025, announced peer-reviewed publication of the Phase 1b trial of sozinibercept combination therapy in diabetic macular edema (DME) in *Translational Vision Science & Technology*.
- In November 2024, appointed Kathy Connell to Board of Directors.
- In October 2024, appointed Parisa Zamiri, MD, PhD as Chief Medical Officer, and Tom Reilly as Chief Financial Officer.
- In September 2024, joined the S&P/ASX 300 Index, completed Drug Substance PPQ campaign, and appointed Mike Campbell as Chief Commercial Officer.

- In July 2024, announced results of A$55.9 million (US$36.9 million) retail entitlement offer, representing the final stage of the approximately A$227.3 million (US$150.0 million) capital raising initiated in June 2024, and published a scientific review of VEGF-C/D signaling pathways in the peer-reviewed journal *Ophthalmology and Therapy*.

Balance Sheet and Liquidity Highlights

- Cash and cash equivalents at December 31, 2024 totaled US$131.9 million.
- Net Cash Flows Used in Operating Activities during the six-months ended December 31, 2024 of US$72.6 million compared to US$69.4 million in the prior year period.

Financial Results and Highlights

For the half year ended December 31, 2024, Opthea reported results compared to the half year ended December 31, 2023:

- Net loss of US$131.9 million, compared to a net loss of US$101.7 million, due to $26.7 million of fair value of investor options, $11.7 million interest expense associated with the development funding agreement and partially offset by $8.7 million decrease in operating expenses.
- Net loss per share (diluted in cents) of US$10.82 compared to a net loss per share (diluted in cents) of US$17.18 due to an increase in weighted ordinary shares issued of 627.3 million from the June/July 2024 financing.
- Operating Expenses (Research and Development and Administrative Expenses) totaled US$85.3 million, compared to US$93.9 million, primarily driven by the advancement of sozinibercept's global Phase 3 pivotal clinical program and chemistry, manufacturing and controls (CMC) activities.
- Adjusted Non-IFRS net loss of US$69.8 million compared to Adjusted Non-IFRS net loss of US$84.3 million, with an Adjusted Non-IFRS net loss per share (diluted in cents) of US$5.73, compared to Adjusted Non-IFRS net loss per share (diluted in cents) of US$14.25, impacted by the increase in ordinary shares outstanding.

For more detailed information, see Opthea's 2025 Half-Year Report as lodged 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 28, 2025. The report can be accessed without charge at www.sec.gov. A copy can also be accessed on the investor section of the www.opthea.com website.

About Sozinibercept

Sozinibercept is a novel, first-in-class VEGF-C/D 'trap' inhibitor designed to be used in combination with standard-of-care anti-VEGF-A therapies to improve vision in wet AMD patients, many of whom respond sub-optimally or become refractory to existing therapies. VEGF-C and VEGF-D are known to independently stimulate retinal angiogenesis and vascular leakage and permeability, while VEGF-A inhibition can also lead to the upregulation of VEGF-C and VEGF-D. Research shows that the targeted inhibition of VEGF-C and VEGF-D with sozinibercept can

prevent blood vessel growth and vascular leakage, which both contribute to the pathophysiology of retinal diseases, including wet AMD. Sozinibercept has the potential to become the first therapy in 20 years to improve visual outcomes in patients with wet AMD, enabling them to live more independently and have a better quality of life.

About Opthea's Clinical Development Program

The Company is currently conducting two fully enrolled, pivotal Phase 3 multicenter, double-masked, randomized clinical trials, COAST (Combination OPT-302 with Aflibercept Study) and ShORe (Study of OPT-302 in combination with Ranibizumab), designed to assess the safety and superior efficacy of sozinibercept combination therapy versus standard-of-care anti-VEGF-A therapies for the treatment of wet AMD. Opthea's Phase 3 clinical trial program is designed to support a broad label and, if successful, sozinibercept has the potential to be approved for use in combination with any anti-VEGF-A for the treatment of wet AMD patients. Sozinibercept has received Fast Track Designation from the US FDA for the treatment of wet AMD. To learn more about Opthea's Phase 3 clinical trial program, please visit ClinicalTrials.gov for COAST, NCT04757636, and ShORe, NCT04757610.

In Opthea's prospective, randomized and controlled Phase 2b trial including 366 treatment-naïve wet AMD patients, sozinibercept was administered in combination with standard-of-care ranibizumab for the treatment of wet AMD. Sozinibercept combination therapy 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 with the combination therapy, including more patients gaining vision of 10 or more EDTRS letters, improved anatomy, with a reduction in swelling and vascular leakage, and a favorable safety profile. These statistically significant results were published in *Ophthalmology* in February 2023.

About Wet AMD

Wet AMD remains the leading cause of vision loss in the elderly, impacting about 3.5 million people in the US and Europe alone. The unmet medical need in wet AMD is significant, with many patients failing to achieve optimal vision outcomes or even losing vision over time, despite treatment with anti-VEGF-A therapies.

About Opthea

Opthea (ASX/NASDAQ:OPT) is a biopharmaceutical company developing novel therapies to treat vision-threatening eye diseases, including wet age-related macular degeneration (wet AMD) and diabetic macular edema (DME), which remain leading causes of vision loss worldwide.

Opthea's lead product candidate in Phase 3 development, sozinibercept, is a first-in-class VEGF-C/D 'trap' inhibitor being evaluated in combination with standard-of-care anti-VEGF-A therapies to deliver superior vision to wet AMD patients. Sozinibercept has the potential to become the first therapy in 20 years to enable patients with wet AMD to live fuller and healthier lives.

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 and the program being designed to support a broad label, the potential for sozinibercept as a combination therapy to be the first therapy in 20 years to achieve superior visual outcomes over anti-VEGF-A therapy alone, and improve vision outcomes for patients with wet AMD and enable them to live fuller and healthier lives, the expected timing for top-line data for Opthea’s Phase 3 clinical trials of sozinibercept, the expected timing for the potential BLA submission, the potential launch of sozinibercept in wet AMD, and the anticipated cash runway. 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 ability to continue as a going concern, the development, testing, production, marketing and sale of drug treatments, regulatory risk and potential loss of regulatory approvals, ongoing clinical studies to demonstrate sozinibercept’s safety, tolerability and therapeutic efficacy, analysis of data from Opthea’s Phase 3 clinical trials, clinical research organization, contract development manufacturing 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 2024 Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission (the “SEC”) on August 30, 2024, Opthea’s 2025 Half Year Report included as an exhibit to the Form 6-K filed with the SEC on February 28, 2025, 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.

Non-IFRS Financial Measures

To supplement our financial statements, which are prepared and presented in accordance with international financial reporting standards (IFRS) and Australian Accounting Standards (AAS), we use the following non-IFRS and non-AAS (together referred to as “Non-IFRS”) financial measures, some of which are discussed above: adjusted net loss, adjusted net loss per share, and adjusted operating expense (also referred to herein as Adjusted Non-IFRS net loss, Adjusted Non-IFRS net loss per share and Adjusted Non-IFRS operating expense). For reconciliations of Non-IFRS measures to the most directly comparable IFRS measures, please see the “Reconciliation of IFRS to Non-IFRS Financial Measures” and “Reconciliation of IFRS Net Loss Per Share to Adjusted Net Loss Per Share (Non-IFRS)” tables in this press release.

We believe these Non-IFRS financial measures provide investors with useful supplemental information about the financial performance of our business, enable comparison of financial results between periods, where certain items may vary independently of business performance, and allow for greater transparency with respect to key metrics used by management in operating our business.

The presentation of these financial measures is not intended to be considered in isolation from, or as a substitute for, financial information prepared and presented in accordance with IFRS and AAS. Investors are cautioned that there are material limitations associated with the use of Non-IFRS financial measures as an analytical tool. In particular, the adjustments to our IFRS financial measures reflect the exclusion of stock-based compensation expense, non-cash Development Funding Agreement (DFA) interest, and non-cash Investor Option fair value adjustments (as defined in the footnote below). In addition, these measures may be different from Non-IFRS financial measures used by other companies, limiting their usefulness for comparison purposes. We compensate for these limitations by providing specific information regarding the IFRS amounts excluded from these Non-IFRS financial measures.

OPTHEA LIMITED
Condensed Consolidated Statements of Financial Position
as of December 31, 2024 and June 30, 2024

	December 31, 2024	June 30, 2024
	US$ (000's)	US$ (000's)
Current assets:		
Cash and cash equivalents	131,916	172,471
Current tax receivable	5,988	10,398
Receivables	1,996	1,426
Prepayments (includes amounts owed by related parties $2,700 (June 2024; $2,724))	4,224	3,897
Total current assets	**144,124**	**188,192**
Non-current assets:		
Property and equipment, net	2	48
Right-of-use assets	42	84
Prepayments (includes amounts owed by related parties $1,600 (June 2024; $450))	1,602	467
Total non-current assets	**1,646**	**599**
Total assets	**145,770**	**188,791**
Current liabilities:		
Payables	30,032	38,104
Lease liabilities	38	93
Derivative financial liabilities - investor options	60,518	24,840
Provisions	1,159	1,018
Total current liabilities	**91,747**	**64,055**
Non-current liabilities:		
Financial liabilities - DFA (includes amounts owed by related parties $157,209 (June 2024; $141,555))	222,714	200,536
Provisions	14	10
Total non-current liabilities	**222,728**	**200,546**
Total liabilities	**314,475**	**264,601**
Net Assets	**(168,705)**	**(75,810)**
Equity		
Contributed equity:ordinary shares	497,468	466,084
Accumulated losses	(711,622)	(579,704)
Reserves	45,449	37,810
Total Equity	**(168,705)**	**(75,810)**

OPTHEA LIMITED
Condensed Consolidated Statements of Profit or Loss and Other Comprehensive Income
For the half year ended December 31, 2024 and 2023

	December 31	
	2024	**2023**
	US$ (000's)	**US$ (000's) Restated**
Revenue	24	61
Other income	125	141
Total Revenue	**149**	**202**
Research and development (includes amounts paid to related parties $2,590, 2023 $4,325)	(69,714)	(87,240)
Administration expenses (includes amounts paid to related parties $175; 2023 Nil)	(15,549)	(6,699)
Total operating expense	**(85,263)**	**(93,939)**
Operating Loss	**(85,114)**	**(93,737)**
Finance income	3,833	1,798
Interest expense on DFA	(22,178)	(10,499)
Gain on remeasurement of financial liability - DFA	—	387
Fair value loss on derivatives - investor options	(32,234)	(5,500)
Net foreign exchange gain/(loss)	(2,199)	827
Loss before income tax	**(137,892)**	**(106,723)**
Income tax benefit	5,975	5,038
Loss for period	**(131,917)**	**(101,685)**
Other comprehensive income		
Items that will not be reclassified subsequently to profit or loss:		
Fair value gains on investments in financial assets	—	—
Other comprehensive income for the period	—	—
Total comprehensive loss for the year	**(131,917)**	**(101,685)**
Earnings per share for loss attributable for the ordinary equity holders of the parent:		
- Basic and diluted loss per share (cents)	(10.82)	(17.18)

OPTHEA LIMITED
Reconciliation of IFRS to Non-IFRS Financial Measures
For the half year ended December 31, 2024 and 2023

	December 31	
	2024	2023
	US$ (000's)	US$ (000's) Restated
Loss for period	(131,917)	(101,685)
Add-back: Interest expense on DFA	22,178	10,499
Add-back: Fair value loss on derivatives - investor options	32,234	5,500
Add-back: Stock-based compensation & depreciation	7,688	1,739
Less: Gain on remeasurement of financial liability - DFA	—	(387)
Adjusted loss for period	(69,817)	(84,334)
Operating Expense	(85,263)	(93,939)
Add-back: Stock-based compensation & depreciation	7,688	1,739
Adjusted Operating Expense	(77,575)	(92,200)

OPTHEA LIMITED
Reconciliation of IFRS Net Loss Per Share to Non-IFRS Adjusted Net Loss Per Share
For the half year ended December 31, 2024 and 2023

	December 31	
	2024 US$	2023 US$ Restated
Net loss per share (basic and diluted in cents)	(10.82)	(17.18)
Add-back: Interest expense on DFA	1.82	1.77
Add-back: Fair value loss on derivatives - investor options	2.64	0.93
Add-back: Stock-based compensation & depreciation	0.63	0.29
Less: Gain on remeasurement of financial liability - DFA	—	(0.07)
Adjusted loss per share (basic and diluted in cents)	(5.73)	(14.25)
Weighted average number of ordinary shares adjusted for the effect of dilution	1,219,199,313	591,881,077

Authorized for release to ASX by Frederic Guerard, CEO

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