Opthea Reports Full-Year Financial Results and Business Updates

August 30, 2024

Completed patient enrollment in COAST and ShORe pivotal wet AMD trials

Financings extended cash runway through topline data readout of both trials in CY2025

Leadership appointments in preparation for regulatory filing and launch of sozinibercept

MELBOURNE, Australia, and PRINCETON, N.J., Aug. 30, 2024 (GLOBE NEWSWIRE) -- 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 twelve months ended June 30, 2024, and highlighted recent corporate and clinical updates.

"During the 2024 fiscal year, we made outstanding progress in advancing sozinibercept's Phase 3 wet AMD program," said Frederic Guerard, PharmD, Chief Executive Officer of Opthea. "We completed enrollment in both COAST and ShORe pivotal trials evaluating the superiority of sozinibercept combination therapy."

"We strengthened our balance sheet with nearly US$300 million in financing proceeds, and expect existing cash and cash equivalents to fund the Company through the anticipated topline data readouts of COAST in early Q2 calendar year 2025 and ShORe in mid calendar year 2025," Dr. Guerard continued. "The funds will also be used to progress Chemistry, Manufacturing, and Controls (CMC) activities, Biologics License Application (BLA) preparations for FDA approval, and continue to ready our organization for a potential launch of sozinibercept in wet AMD."

Anticipated Milestones

- Phase 3 topline results from COAST, expected in early Q2 CY 2025.
- Phase 3 topline results from ShORe, expected by mid-CY 2025.

Corporate Highlights

- ***Completed enrollment in sozinibercept pivotal trials, one of the largest Phase 3 programs in wet AMD*** — Opthea's Phase 3 clinical program consists of two multicenter, double-masked, randomized trials, COAST and ShORe, which enrolled close to 2,000 treatment-naïve wet AMD patients in total in over 300 global sites. Enrollment of COAST completed in February 2024, and ShORe in May 2024.

- ***Successfully raised US$295.1 million to extend runway through topline data readouts of Phase 3 program*** — During the fiscal year, Opthea completed three financings: (1) a placement and partially underwritten entitlement offer raising US$151.9 million[1], (2) the remaining US$35.0 million commitment under the Development Funding Agreement (DFA) as well as a further US$50.0 million under an amended DFA with a new co-investor, and (3) a placement and fully underwritten entitlement offer raising $58.2 million.

- ***Strengthened organization with key leadership appointments to support sozinibercept development and launch preparations*** — During the fiscal year, Opthea welcomed accomplished biopharmaceutical executives and leaders with extensive experience in ophthalmology:

    - Frederic Guerard, PharmD, and Peter Lang, MBA, joined as **Chief Executive Officer** and **Chief Financial Officer**, respectively, to establish a US-based executive leadership team, with the transition of Megan Baldwin, PhD, to the role of **Founder and Chief Innovation Officer** (October 2023).
    - Arshad M. Khanani MD, MA, FASRS, a global thought leader and principal investigator for numerous clinical trials in retinal diseases, joined as **Chief Medical Advisor** to support sozinibercept clinical development and launch preparations (February 2024).
    - Julie Clark, MD, and Fang Li, PhD, joined as **SVP Clinical Development** and **SVP Regulatory Affairs**, respectively, to lead the clinical development, regulatory strategy, and potential filings for sozinibercept in the US and other markets (February 2024).
    - John Han, PharmD, joined as **VP Medical Affairs** to define and execute the Company's medical and scientific affairs strategies (April 2024).
    - Sujal Shah joined the **Board of Directors** and assumed the role of **Audit and Risk Committee Chair**, bringing extensive leadership and product development experience to the Company (April 2024).

- ***Presented evidence of sozinibercept's potential to be the first therapy in 20 years to improve visual outcomes in patients with wet AMD*** — The Company hosted a Key Opinion Leader Event featuring presentations from global retina experts Arshad M. Khanani, MD, MA, FASRS, Charles C. Wykoff, MD, PhD, and Veeral S. Sheth, MD, MBA, FACS, FASRS (April 2024), and published a review article outlining the scientific rationale for sozinibercept as a potential treatment for wet AMD in the peer-reviewed journal *Ophthalmology and Therapy* (June 2024).

- ***Formed Medical Advisory Board to advise on short- and long-term strategic direction of pipeline*** — Opthea welcomed 10 world-renowned retina thought leaders to join its Medical Advisory Board to inform the Company's medical decisions as it prepares for market readiness of sozinibercept in wet AMD (July 2024).

Financial Results and Highlights

For the fiscal year ended June 30, 2024, Opthea reported results compared to the fiscal year ended June 30, 2023:

- Net loss of US$220.2 million, an increase of 55%, compared to a net loss of US$142.5 million, with a net loss per share (diluted in cents) of US$34.51 compared to a net loss per share (diluted in cents) of US$32.20.
- Adjusted Non-IFRS net loss of US$174.0 million compared to Adjusted Non-IFRS net loss of US$135.5 million, a 28% increase, with an Adjusted Non-IFRS net loss per share (diluted in cents) of US$27.27 compared to Adjusted Non-IFRS net loss per share (diluted in cents) of US$30.61.
- Operating Expenses (Research and Development and Administrative Expenses) totaled US$192.1 million, compared to US$150.4 million, primarily driven by the advancement of sozinibercept's global Phase 3 pivotal clinical program and CMC activities.
- Adjusted Non-IFRS Operating Expenses totaled US$187.0 million compared to US$144.6 million.

Balance Sheet and Liquidity Highlights

- Cash and cash equivalents on June 30, 2024 totaled US$172.5 million. Pro-forma for the 2024 Retail Entitlement Offer which closed in July 2024, cash balance is approximately US$207.3 million.
- Net Cash Flows Used in Operating Activities of (US$161.0) million compared to (US$120.6) million.

Upcoming Investor and Medical Conferences

- September 9, 2024, H.C. Wainwright Global Investor Conference, New York
- September 17, 2024, Cantor Global Healthcare Conference, New York
- September 18, 2024, EURETINA Innovation Spotlight, Barcelona, Spain
- September 19-22, 2024, EURETINA Congress, Barcelona, Spain

For more detailed information, see Opthea's 2024 Full Year 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 August 30, 2024, and Opthea's 2024 Annual Report on 20-F as filed with the SEC on August 30, 2024. 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 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 clinical 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 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 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 fully enrolled 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 standard-of-care anti-VEGF-A agents. To learn more, visit our website at www.opthea.com and follow us on X and LinkedIn.

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 in 20 years to achieve superior visual outcomes over anti-VEGF-A therapy alone, and improve vision outcomes for patients with wet AMD, the expected timing for top-line data for Opthea's Phase 3 clinical trials of sozinibercept, the anticipated cash runway, and the expected use of proceeds from the financing. 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's safety, tolerability and therapeutic efficacy, analysis of data from Opthea's Phase 3 clinical trials, 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 August 30, 2024, 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.

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 independent 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
Consolidated Statements of Financial Position
as of June 30, 2024, and 2023

	June 30, 2024	June 30, 2023
	US$	US$
Assets		
Current assets:		
Cash and cash equivalents	172,471,346	89,188,713
Current tax receivable	10,398,039	5,926,350
Receivables	1,426,400	636,564
Prepayments (includes amounts owed by related parties $2,724,238 (2023: $nil))	3,896,779	2,634,671
Total current assets	188,192,564	98,386,298
Non-current assets:		
Property and equipment, net	47,725	33,035
Right-of-use assets	84,226	168,451
Prepayments (includes amounts owed by related party $450,000 (2023: $nil))	466,701	53,535
Total non-current assets	598,652	255,021
Total assets	188,791,216	98,641,319
Liabilities		
Current liabilities:		
Payables	38,104,421	17,891,854
Lease liabilities	93,033	97,485
Derivative financial liabilities - investor options	24,840,456	—
Provisions	1,017,748	753,300
Total current liabilities	64,055,658	18,742,639
Non-current liabilities:		
Lease liabilities	—	84,226
Financial liabilities - DFA (includes amounts due to a related party $141,554,653 (2023: $85,660,000))	200,535,758	85,660,000
Provisions	9,877	7,631
Total non-current liabilities	200,545,635	85,751,857
Total liabilities	264,601,293	104,494,497
Net Assets	(75,810,077)	(5,853,178)
Equity		
Contributed equity	466,084,145	320,883,552
Accumulated Loss	(579,704,543)	(359,462,438)
Reserves	37,810,321	32,725,708
Total Equity	(75,810,077)	(5,853,178)

OPTHEA LIMITED
Consolidated Statements of Profit or Loss and Other Comprehensive Income
For the Years ended June 30, 2024, and 2023

	Years ended June 30, 2024	2023
	US$	US$
Revenue	124,666	108,406
Other income	137,193	276,869
Operating expenses:		
Research and development (includes amounts owed by related parties $3,042,762 (2023: $900,000))	(176,326,321)	(128,828,888)
Administration expenses	(15,778,271)	(21,582,181)
Total operating expenses	(192,104,592)	(150,411,069)
Operating Loss	**(191,842,733)**	**(150,025,794)**
Finance income	3,394,726	3,227,496
Interest expense on DFA* (includes amounts owed to related party $24,698,653 (2023: $13,462,160))	(30,263,042)	(13,462,160)

Gain on remeasurement of financial liability - DFA	387,284	12,302,160
Fair value loss on derivative - investor options	(11,223,535)	—
Net foreign exchange (loss)/gain	(107,001)	(489,137)
Loss before income tax	**(229,654,301)**	**(148,447,435)**
Income tax benefit	9,412,196	5,926,350
Loss for the year	**(220,242,105)**	**(142,521,085)**
Other comprehensive income		
Other comprehensive income for the period, net of tax	—	—
Total comprehensive loss for the year	**(220,242,105)**	**(142,521,085)**
Loss for the year is attributable to:		
Owners of the Company	(220,242,105)	(142,521,085)
Net loss	**(220,242,105)**	**(142,521,085)**
Total comprehensive loss for the year is attributable to:		
Owners of the Company	(220,242,105)	(142,521,085)
Comprehensive loss	**(220,242,105)**	**(142,521,085)**
Loss per share attributable to the owners of the Company:		
- Basic and diluted loss per share (cents)	**(34.51)**	**(32.20)**

* Development Funding Agreement ("DFA")

OPTHEA LIMITED
Reconciliation of IFRS to Non-IFRS Financial Measures
For the Years ended June 30, 2024, and 2023

	Years ended June 30,	
	2024	**2023**
	US$	**US$**
Loss for the year	(220,242,105)	(142,521,085)
Add-back: Interest expense on DFA	30,263,042	13,462,160
Add-back: Fair value loss on derivative - investor options	11,223,535	—
Add-back: Stock-based compensation & depreciation	5,103,412	5,851,687
Less: Gain on remeasurement of financial liability - DFA	(387,284)	(12,302,160)
Adjusted Loss for the year	**(174,039,400)**	**(135,509,398)**
Operating expense	(192,104,592)	(150,411,069)
Add-back: Stock-based compensation & depreciation	5,103,412	5,851,687
Adjusted Operating expense	**(187,001,180)**	**(144,559,382)**

OPTHEA LIMITED
Reconciliation of IFRS Net Loss Per Share to Non-IFRS Adjusted Net Loss Per Share
For the Years ended June 30, 2024, and 2023

	Years ended June 30,	
	2024	**2023**
	US$	**US$**
Net loss per share (basic and diluted in cents)	(34.51)	(32.20)
Add-back: Interest expense on DFA	4.74	3.04
Add-back: Fair value loss on derivative - investor options	1.76	—
Add-back: Stock-based compensation & depreciation	0.80	1.32
Less: Gain on remeasurement of financial liability - DFA	(0.06)	(2.77)
Adjusted loss per share (basic and diluted in cents)	**(27.27)**	**(30.61)**

Weighted average number of ordinary shares adjusted for the Effect of dilution	638,202,922	442,637,406

Authorized for release to ASX by Frederic Guerard, CEO

Investor and Media Inquiries

PJ Kelleher
LifeSci Advisors, LLC
Email: pkelleher@lifesciadvisors.com
Phone: 617-430-7579

Join our email database to receive program updates:
Tel: +61 (0) 3 9826 0399, Email: info@opthea.com Web: www.opthea.com

Source: Opthea Limited

1) On July 15, 2024, Opthea announced the completion of the Retail Entitlement offer raising approximately US$37.6 million, following the completion of the Institutional Entitlement Offer and Institutional Placement raising approximately US$114.3 million on June 13, 2024.

Source: Opthea Limited