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 January, 2025

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 Announces Publication in Diabetic Macular Edema**

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: 01/07/2025

Exhibit 99.1

ASX, Nasdaq and Media Release

January 7, 2025

Opthea Announces Publication in Diabetic Macular Edema

Phase 1b clinical data underpins sozinibercept's potential as a novel, first-in-class VEGF-C/D 'trap' to improve visual and anatomic outcomes in DME

Published in peer-reviewed journal Translational Vision Science & Technology and included in the Anti-VEGF Special Journal Issue of ARVO

DME program to be advanced after wet AMD topline data readout anticipated for COAST in early CY Q2 2025 and ShORe in mid-2025

Melbourne, Australia and Princeton, NJ, January 7, 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 the publication of its Phase 1b trial of sozinibercept combination therapy in diabetic macular edema (DME) in the peer-reviewed journal *Translational Vision Science & Technology (TVST*), issued on December 19, 2024.

The publication, *Phase 1b Dose Escalation Study of Sozinibercept Inhibition of Vascular Endothelial Growth Factors C and D With Aflibercept for Diabetic Macular Edema*, evaluated the outcomes in previously anti-VEGF-A monotherapy treated patients with persistent DME, a difficult-to-treat patient population. The article was also included in the Anti-VEGF Special Journal Issue of TVST, the official Journal of The Association for Research in Vision and Ophthalmology (ARVO).

"The DME trial results underpin sozinibercept's potential as a novel, first-in-class VEGF-C/D 'trap' to elevate the standard of care in retinal diseases including DME, by preventing blood vessel growth and vascular leakage in the retina and delivering improved visual and anatomic outcomes when combined with standard-of-care anti-VEGF-A therapies," said Frederic Guerard, PharmD, Chief Executive Officer of Opthea. "Whilst our immediate focus is to prepare for the anticipated sozinibercept Phase 3 topline data readout in wet AMD of COAST in early CY Q2 2025 and ShORe in mid-2025, we also plan to advance our clinical development program of sozinibercept in DME."

In this first-in-human, open-label, multicenter, dose escalating Phase 1b DME trial, nine patients received sozinibercept (0.3, 1, or 2 mg) in combination with aflibercept (2 mg) once every four weeks for twelve weeks. The primary endpoint was safety, and the secondary endpoints included mean change from baseline in best-corrected visual acuity (BCVA) and anatomical parameters, including central subfield thickness (CST). Sozinibercept combination therapy was well tolerated with no dose-limiting toxicities. The trial also demonstrated a dose-response relationship of increased gains in BCVA for ascending doses of sozinibercept, with the 2 mg sozinibercept combination arm demonstrating the highest BCVA gain. All sozinibercept doses demonstrated a meaningful CST reduction. These data, published in TVST, support the further investigation of sozinibercept as a treatment for DME, a disease with rapidly increasing prevalence and unmet medical need.

Diabetic macular edema is the leading cause of central vision loss in people living with diabetes. It is estimated to affect around 19 million people worldwide, and with the rise of diabetes, the prevalence is expected to increase to 29 million by 2045. DME occurs when blood vessels in the retina swell and leak, leading to fluid accumulation in the retina.

Anti-VEGF-A therapies are the current standard of care for DME patients. There is an unmet need for early intervention to prevent irreversible damage of the retina, as well as improve visual outcomes for patients treated with anti-VEGF-A therapies alone, which may lead to suboptimal vision outcomes.

About Opthea

Opthea (ASX/NASDAQ:OPT) is a biopharmaceutical company developing novel therapies to address the unmet needs 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 therapies to improve overall efficacy and deliver superior vision gains compared to standard-of-care anti-VEGF-A agents alone.

To learn more, visit our website at www.opthea.com and follow us on X and LinkedIn.

Forward-Looking Statements

This ASX announcement contains certain forward-looking statements, including within the meaning of the US 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 the potential importance of VEGF-C and VEGF-D signaling pathways to the pathogenesis of retinal diseases, sozinibercept's potential as a novel, first-in-class VEGF-C/D 'trap' to improve visual and anatomic outcomes in DME and prevent blood vessel growth and vascular leakage in the retina, soziniberceipt's potential to deliver superior visual outcomes in wet AMD when combined with standard-of-care anti-VEGF-A therapies, the potential for the registrational program for sozinibercept in wet AMD, and the anticipated timing for the results of the COAST and ShORe Phase 3 wet AMD trials and the potential for such results to support a broad label and, if successful, enable sozinibercept to be approved for use in combination with any anti-VEGF-A for the treatment of wet AMD patients and sozinibercept's clinical development in and potential as a treatment for diabetic macular edema and the expected prevalence of DME. 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, 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 US Securities and Exchange Commission (the "SEC") on August 30, 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 Frederic Guerard, PharmD, CEO

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Source: Opthea Limited