# 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 April 2024

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  $\boxtimes$  Form 40-F  $\square$ 

# EXHIBIT INDEX

Exhibit	Description				
99.1	Press Release: Opthea Appoints Sujal Shah to the Board of Directors				

# **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: 04/04/2024



# ASX, Nasdaq and Media Release

4 April 2024

# Opthea Appoints Sujal Shah to the Board of Directors

Former CymaBay Therapeutics CEO brings extensive leadership experience to his role as a Non-Executive

Director and Audit and Risk Committee Chair

Melbourne, Australia and Princeton, NJ, April 4, 2024 -- 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 appointment of Sujal Shah to the Company's Board of Directors (the "Board"), effective April 4, 2024. Concurrent with his appointment as non-Executive Director, Mr. Shah will also become Chairman of the Audit and Risk Committee. In conjunction with Mr. Shah's appointment, the Company also announced that Daniel Spiegelman has resigned from the Board in his role as Non-Executive Director and as Chairman of the Audit and Risk Committee.

Mr. Shah is an accomplished biopharmaceutical executive with extensive leadership and product development experience and a track record in capital formation that complements the deep expertise in retinal disease, especially wet AMD, of the Opthea Board. Most recently, Mr. Shah served as President and Chief Executive Officer of CymaBay Therapeutics which was acquired by Gilead Sciences for approximately \$4.3 billion in total equity value in March 2024.

"We are delighted to welcome Sujal to our Board of Directors as we rapidly advance the registrational program for sozinibercept in wet AMD and prepare for key upcoming clinical, regulatory and commercial milestones," said Jeremy Levin, DPhil MB BHir, Chairman of the Opthea Board of Directors. "Sujal's significant experience driving value for biotech companies through successful product and commercial development will be an invaluable resource to the Opthea team as we enter this pivotal growth phase of the company."

"It's a privilege to join the Board of Opthea at such a transformative time," said Sujal Shah. "I look forward to partnering with the executive leadership team and the Board as we continue to drive sozinibercept forward, with the goal of enhancing vision outcomes for patients worldwide."

Dr. Levin concluded by sharing, "On behalf of the Opthea organization, I want to express our gratitude and appreciation to Dan Spiegelman, who will now transition from our Board, for his work as a non-Executive Director and Audit and Risk Committee Chairman. We are very grateful for Dan's contribution to the Company."



#### **About Sujal Shah**

Mr. Shah brings two decades of experience as a biopharmaceutical executive and strategic advisor to the Opthea Board. Most recently, Mr. Shah served as President and Chief Executive Officer at CymaBay Therapeutics, a clinical-stage biopharmaceutical company developing innovative therapies for patients with liver and other chronic diseases. Mr. Shah joined CymaBay as Chief Financial Officer, taking the company public in 2013. Prior to CymaBay, Mr. Shah was a healthcare investment banker for Citigroup Inc. as well as Credit Suisse, where he was responsible for managing client relationships and executing strategic and financing related transactions for clients focused on life sciences.

Mr. Shah currently serves as Chairman of the Board of Tvardi Therapeutics and as a Director on the Board of Stratus Therapeutics. He received an M.B.A. from the Carnegie Mellon University Tepper School of Business and M.S. and B.S. degrees in Biomedical Engineering from Northwestern University.

#### **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 <a href="Ophthalmology">Ophthalmology</a>, 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, 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. To learn more, visit our website and follow us on X and LinkedIn.

LUCENTIS<sup>®</sup> 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 rapidly advancing the registrational program for sozinibercept in wet AMD, expectations regarding the pivotal growth phase of Opthea, and the ability of sozinibercept to enhance vision outcomes for patients worldwide. 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 the 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

## **Investor Enquiries**

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