



Opthea Announces Placement and Partially Underwritten Entitlement Offer to Raise up to Approximately A\$227.3 million (US\$150.0 million¹)

June 12, 2024

Financing extends Opthea's cash runway through Phase 3 topline data readout for both pivotal trials of sozinibercept in wet AMD

Phase 3 topline data readout accelerated for COAST to early Q2 calendar year 2025, and anticipated for ShORe in mid-calendar year 2025

MELBOURNE, Australia and PRINCETON, N.J., June 11, 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 that the Company is seeking to raise up to approximately A\$227.3 million (US\$150.0 million¹) via an approximately A\$10.0 million (US\$6.6 million¹) placement ("**Placement**") and an approximately A\$217.3 million (US\$143.4 million¹) Accelerated Non-Renounceable Entitlement Offer ("**ANREO**" or "**Entitlement Offer**").

The Company expects the net proceeds from the Placement and Entitlement Offer, together with cash on hand, to fund the Company, through the anticipated Phase 3 topline data readouts for COAST (Combination OPT-302 with Aflibercept Study), and ShORe (Study of OPT-302 in combination with Ranibizumab). The funds are also intended to be used to progress chemistry, manufacturing, and controls (CMC) activities, Biologics License Application (BLA) preparations for FDA approval, and for general corporate purposes.

Based on the completion of enrollment in COAST in February 2024 and ShORe in May 2024, as well as Opthea's internal expansion of its clinical development team, the topline data readout of COAST is now accelerated to early in the second calendar quarter of 2025, and the topline data readout for ShORe is anticipated in mid-calendar year 2025.

"This institutional Placement and Entitlement Offer will strengthen Opthea's cash position, and we expect to fund operations through the anticipated topline data readouts of both our pivotal trials, which have enrolled a total of 1,984 wet AMD patients. Opthea also plans to complete the manufacturing of the commercial-scale drug batches required for the BLA," said Fred Guerard, PharmD, Chief Executive Officer of Opthea. "We are excited about the potential for sozinibercept to become the first treatment in over 15 years to demonstrate superior vision outcomes in wet AMD when combined with standard-of-care anti-VEGF-A therapies."

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 needs in wet AMD are still significant, with many patients failing to achieve optimal vision outcomes despite treatment with anti-VEGF-A therapies.

Sozinibercept is a novel, first-in-class VEGF-C/D 'trap' designed to be used in combination with standard-of-care anti-VEGF-A 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.

The sozinibercept Phase 3 program is designed to assess the safety and superior efficacy of sozinibercept in combination with standard-of-care anti-VEGF-A therapies compared to standard-of-care alone for the treatment of patients with wet AMD.

1. Assumes AUD/USD exchange rate of A\$1.00/US\$0.66

1. Capital Raising overview

Opthea is pleased to announce the launch of a capital raising comprising:

- A 1 for 1.22 pro-rata accelerated non-renounceable entitlement offer of new fully paid ordinary shares in OPT (**New Shares**) to certain eligible shareholders (**Entitlement Offer**), together with one option to acquire one fully paid ordinary share in Opthea (Option) for every three New Shares issued under the Entitlement Offer, to raise up to approximately A\$217.3 million (US\$143.4 million¹); and
- Placement of New Shares to certain institutional and sophisticated investors (**Placement**), together with one Option to acquire one fully paid ordinary share in Opthea for every three New Shares issued under the Placement, to raise up to approximately A\$10.0 million (US\$6.6 million¹)

(collectively, the **Offer** or **Capital Raising**).

The offer price for the Placement and Entitlement Offer will be A\$0.40 per New Share (**Offer Price**), representing a discount of:

- 17.5% to the last closing price on Thursday 6 June 2024 of A\$0.485 per share;
- 33.9% to the 30 day volume-weighted average price of A\$0.605 per share; and

- 10.3% to the TERP of A\$0.446² per share.

Each New Share issued under the Capital Raising will rank equally with existing fully paid ordinary shares in OPT from the date of issue.

MST Financial Services Pty Ltd (**MST**) will act as placement agent (in respect of the Placement), lead manager and bookrunner (in respect of the Entitlement Offer) and sole partial underwriter to the Entitlement Offer with Bell Potter Securities Limited serving as co-manager. BofA Securities and Leerink Partners are also advising the Company in connection with the transactions.

1. Assumes AUD/USD exchange rate of A\$1.00/US\$0.66

2. TERP means that “theoretical ex right price” at which OPT shares should trade immediately after the ex-date of the Offer and is adjusted for New Shares to be issued under the Placement. TERP is a theoretical calculation only and the actual price at which OPT’s shares trade at that time will depend on many factors and may not be equal to the TERP.

2. Capital Raising details

Placement

The Placement is expected to raise up to approximately A\$10.0 million (US\$6.6 million¹) in gross proceeds and is being undertaken utilizing the Company’s existing placement capacity under ASX Listing Rule 7.1. The Placement is not underwritten.

The Company in its sole discretion reserves the right to raise additional funds under the Placement. Any New Shares and New Options issued as a result of raising such additional funds will be issued within Opthea’s available placement capacity under ASX Listing Rule 7.1.

Entitlement Offer

The partially underwritten Entitlement Offer of up to A\$217.3 million (US\$143.4 million¹) will consist of a 1 for 1.22 pro-rata accelerated non-renounceable entitlement offer.

The Entitlement Offer will be conducted on the basis of the shares held by eligible shareholders as at AEST 7:00pm (Melbourne time) on Friday, 14 June 2024 (**Record Date**).

All New Shares issued under the Entitlement Offer will be issued at the Offer Price.

The Entitlement Offer is non-renounceable and accordingly entitlements will not be tradeable on the ASX or be otherwise transferable. Shareholders who do not take up their full entitlement will not receive any payment in respect of the entitlements they do not take up and their percentage equity interest in Opthea will be diluted.

OPT shares will remain in a trading halt pending completion and announcement of the Placement and the institutional component of the Entitlement Offer (**Institutional Entitlement Offer**).

For the avoidance of doubt, holders of the Company’s American Depositary Shares (Nasdaq:OPT) are not eligible to participate in the Entitlement Offer or receive New Options.

Institutional Entitlement Offer

Eligible institutional and sophisticated shareholders (**Institutional Shareholders**) will be invited to participate in the Institutional Entitlement Offer which will commence on Wednesday, 12 June 2024.

Institutional Shareholders may opt to take up all, part or none of their entitlements. Entitlements not taken up by Institutional Shareholders, together with those entitlements of ineligible institutional and retail shareholders, will be offered to other institutional and sophisticated investors at the Offer Price.

The Institutional Entitlement Offer will be made under a transaction specific prospectus issued under section 713 of the *Corporations Act 2001* (Cth) (**Prospectus**). The Prospectus will be lodged with ASIC and released on the ASX on Wednesday 12 June 2024.

Retail Entitlement Offer

Eligible shareholders who have a registered address in Australia or New Zealand on the register as at 7:00pm (Melbourne time) on the Record Date and who were not invited to participate in the Institutional Entitlement Offer will be invited to participate in the retail component of the Entitlement Offer (**Retail Entitlement Offer**) at the same Offer Price and offer ratio as under the Institutional Entitlement Offer.

The Retail Entitlement Offer is expected to open on Wednesday, 19 June 2024 and close at AEST 5:00pm (Melbourne time) on Wednesday, 10 July 2024.

The Retail Entitlement Offer will be made under the Prospectus. The Prospectus will be lodged with ASIC and released on ASX on Wednesday 12 June 2024 and will be dispatched to eligible retail shareholders, along with personalized application forms, on Wednesday, 19 June 2024. The Prospectus will provide details of how to participate in the Retail Entitlement Offer. Eligible retail shareholders may opt to take up all, part or none of their entitlement. Eligible retail shareholders will also have the opportunity to apply for and be allocated additional New Shares up to 25% of their entitlement (subject to scale back at the sole discretion of Opthea) (**Top-Up Facility**).

Opthea may (in its absolute discretion) extend the Retail Entitlement Offer to any Institutional Shareholder that was eligible to, but was not invited to participate in, the Institutional Entitlement Offer (subject to compliance with relevant laws).

New Options

Participants in the Placement and Entitlement Offer will also be offered one (1) option, each exercisable at A\$1.00 per option and expiring on 30 June 2026 (**New Options**), for every three (3) New Shares subscribed under the Placement and Entitlement Offer. The offer of New Options is made under the Prospectus. No additional consideration is payable in respect of the New Options.

All New Options are expected to be issued upon allotment of the New Shares under the Retail Entitlement Offer and, subject to satisfying spread requirements set out in ASX Listing Rule 2.5, condition 6, the Options are intended to be quoted on the ASX.

The full terms and conditions of the New Options will be set out in the Prospectus. Copies of the Prospectus will be available on the ASX website and at www.opthea.com.

Partial Underwriting

The issue of New Shares (and New Options) under the Entitlement Offer is partially underwritten by MST Financial Services Pty Ltd.

These underwriting arrangements consist of:

- a full underwriting of the Retail Entitlement Offer; and
- a partial underwriting of the Institutional Entitlement Offer of up to A\$30.0 million.

The underwriting is subject to the terms and conditions of the Underwriting Agreement, which are summarised in the Investor Presentation and Prospectus.

1. Assumes AUD/USD exchange rate of A\$1.00/US\$0.66

3. Timetable

The timetable below is indicative only and subject to change. The Company reserves the right to alter the dates below in its full discretion and without prior notice, subject to the ASX Listing Rules and the Corporations Act.

Item	Date
Trading Halt and announcement of the Capital Raising, lodgement of Offer Documents, including Prospectus with ASIC	Wednesday, 12 June 2024
Placement and Institutional Entitlement Offer opens	Wednesday, 12 June 2024
Placement and Institutional Entitlement Offer closes	Thursday, 13 June 2024
Announcement of completion of the Institutional Entitlement Offer and Placement, trading halt lifted, existing securities recommence trading	Friday, 14 June 2024
Record Date for Entitlement Offer	7:00pm on Friday, 14 June 2024
Despatch of Prospectus under Retail Entitlement Offer	Wednesday, 19 June 2024
Retail Entitlement Offer opens	Wednesday, 19 June 2024
Settlement of New Shares issued under the Institutional Entitlement Offer and Placement	Thursday, 20 June 2024
Allotment of New Shares issued under the Institutional Entitlement Offer and Placement	Friday, 21 June 2024
Retail Entitlement Offer closes	7:00pm on Wednesday, 10 July 2024
Announcement of results of the Retail Entitlement Offer and notification of any shortfall under the Retail Entitlement Offer	Monday, 15 July 2024
Settlement of New Shares under the Retail Entitlement Offer and any shortfall under the Retail Entitlement Offer	Tuesday, 16 July 2024
Allotment and issue of New Shares and New Options under the Retail Entitlement Offer, and New Options issued under the Institutional Entitlement Offer and Placement	Wednesday, 17 July 2024
Trading commences on a normal basis for New Shares issued under the Retail Entitlement Offer and New Options under the Entitlement Offer and Placement	Thursday, 18 July 2024
Despatch of holding statements for New Shares issued under the Retail Entitlement Offer and New Options under the Entitlement Offer and Placement	Friday, 19 July 2024

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 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 rapidly advancing the registrational program for sozinibercept in wet AMD, expectations regarding the pivotal growth phase of Opthea, the ability of sozinibercept to enhance vision outcomes for patients worldwide, Opthea’s expected cash runway, the expected timing for topline data readout, and the expected use of proceeds. 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, Opthea’s 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, additional analysis of data from Opthea’s Phase 3 clinical trials, clinical research organization, contract manufacturer; Biologic License Application preparation, corporate 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.

Not An Offer

This ASX announcement is not a disclosure document and should not be considered as investment advice. The information contained in this ASX announcement is for information purposes only and should not be considered an offer or an invitation to acquire Company securities or any other financial products and does not and will not form part of any contract for the acquisition of New Shares.

In particular, this ASX announcement does not constitute an offer to sell, or a solicitation of any offer to buy, any securities in the United States or any other jurisdiction in which such an offer would be illegal or impermissible. The securities to be offered and sold in the Placement and SPP have not been, and will not be, registered under the U.S. Securities Act of 1933, as amended (the “U.S. Securities Act”), or the securities laws of any state or other jurisdiction of the United States. No public offering of securities is being made in the United States. Accordingly, the securities to be offered and sold in the Placement and SPP may only be offered and sold outside the United States in “offshore transactions” (as defined in Rule 902(h) under Regulation S of the U.S. Securities Act (“Regulation S”)) in reliance on Regulation S, unless they are offered and sold in a transaction registered under, or exempt from, or in a transaction not subject to, the registration requirements of, the U.S. Securities Act and applicable U.S. state securities laws.

Authorized for release to ASX by Frederic Guerard, CEO

Investor & 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



Source: Opthea Limited