



ASX and Media Release
19 October 2021

Opthea Chairman's Address to the 2021 Annual General Meeting

Melbourne, Australia; 19 October 2021 – Opthea Limited (ASX:OPT; Nasdaq:OPT),

Good morning to those of you who have joined us from Australia and good afternoon to our US shareholders.

Despite the unparalleled circumstance that our nation, our industry, and our company has faced over the past year against the backdrop of a global pandemic, Opthea has advanced significantly. Today, at our Annual General Meeting we are pleased to share our achievements over the past 12 months and update you on our strategic goals and objectives for the current fiscal year.

At Opthea we are forging a new but important path for wet AMD therapies. Whilst many patients administered anti-VEGF-A therapies experience stabilization or improvement in visual acuity, a majority of patients fail to achieve 20/40 or better vision after 12 months of treatment; and many are unable to resume routine daily activities such as driving and reading. We believe in the potential of OPT-302, a novel and unique molecule, which by blocking VEGF-C and VEGF-D, may address limitations in the efficacy of current treatments for wet AMD and other retinal diseases.

So, as we continue on our development path we are motivated by:

- Most notably the need to improve outcomes for patients with retinal eye diseases;
- And that there have been no new therapies targeting novel mechanisms approved for wet AMD since the approval of the first VEGF-A inhibitor for wet AMD over 15 years ago. If successfully developed, OPT-302 may change that unfortunate circumstance.

We are encouraged in our approach because of the sound scientific rationale for targeting VEGF-C and VEGF-D, which is supported by our Phase 2b trial outcomes demonstrating superior vision gains in patients receiving combination OPT-302 therapy.

From an operational perspective, I am pleased to report that Opthea has continued to successfully advance its two large Phase 3 pivotal registrational clinical trials for OPT-302 in wet AMD.

Building on successful End-of-Phase 2 and Scientific Advice regulatory meetings with the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) respectively, we finalized the Phase 3 development pathway for OPT-302 and in March this year, initiated two global, multi-center, randomized, sham-controlled Phase 3 clinical trials, ShORe and COAST. Over an approximate 18-month period, both trials will each enroll approximately 990 patients from more than 20 countries worldwide.

Earlier in the year the FDA granted Fast-Track status to OPT-302 for the treatment of wet AMD – an acknowledgement of the unmet medical need in the clinical management of wet AMD and the potential of OPT-302 to address that unmet medical need.

Our objective is to report Phase 3 topline data in second half of calendar year 2023.

From a corporate perspective, we completed a U.S. initial public offering (IPO) and NASDAQ listing in October 2020, raising US\$128.2 million (AU\$164.9 million) equity capital.

Additionally, we have strengthened the board. In addition to my appointment as Chairman of the Board in October 2020 we expanded its strengths in clinical and commercialization strategy with the appointments of Dr. Julia Haller and Ms. Judith Robertson as independent non-executive directors. In addition to the board appointment, we are building out our U.S. team with the intent to position the Company for success and increased shareholder value.

Looking ahead, Opthea will focus over the next 12 months on the execution of the Phase 3 pivotal program for OPT-302 in wet AMD and ensuring the company has the resources and capability to take full advantage of the opportunities we believe this unique program offers.

On behalf of the board and management we would like to thank our shareholders for their support and encouragement. We look to the future with enthusiasm and a single-minded dedication to the objective of delivering high value, both to families of those with disorders of the eye and to our shareholders.

Thank you for your support and investment in Opthea.

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 OPT-302 is in pivotal Phase 3 clinical trials and being developed for use in combination with anti-VEGF-A monotherapies to achieve broader inhibition of the VEGF family, with the goal of improving overall efficacy and demonstrating superior vision gains over that which can be achieved by inhibiting VEGF-A alone.

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

Certain statements in this announcement may contain forward-looking statements, including within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statement describing Company goals, expectations, intentions or beliefs is a forward-looking statement and should be considered an at risk statement, including, but not limited to, the continuation of patient recruitment for Opthea's pivotal Phase 3 clinical trials of OPT-302 in wet AMD. Such statements are based on Opthea's current plans, objectives, estimates, expectations and intentions and are subject to certain risks and uncertainties, including risks and uncertainties associated with clinical trials and product development and the impact of general economic, industry or political conditions in Australia, the United States or internationally. These and other risks and uncertainties are described more fully in the section titled "Risk Factors" in the final prospectus filed with the SEC on October 19, 2020. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required under applicable law. You should not place undue reliance on these forward-looking statements as predictions of future events, which statements apply only as of the date of this announcement. Actual results could differ materially from those discussed in this ASX announcement.

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