



ASX Release
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Opthea Completes A\$45 Million Capital Raising

Melbourne, Australia; 28 April 2017 – Opthea Limited (ASX:OPT) (“Opthea”), a developer of novel biologic therapies for the treatment of eye diseases, announced today the completion of its A\$45 million capital raising launched on 3 April 2017. The proceeds from this offering enable the acceleration and diversification of the Company’s clinical development strategy for OPT-302, its novel VEGF-C/D ‘Trap’ therapy for wet age-related macular degeneration (“wet AMD”) and diabetic macular edema (“DME”). Both eye diseases have a major impact on the quality of life for patients and represent leading causes of vision loss in the elderly and working-age populations globally.

The A\$45 million capital raising consisted of a A\$35m placement and a 1 for 14 pro-rata non-renounceable entitlement offer, comprising a A\$7m institutional component that closed on 5 April 2017 and a A\$3m retail component that closed on 24 April 2017 (“Retail Entitlement Offer”). New shares subscribed for under the Retail Entitlement Offer are expected to be issued on 3 May 2017 and will commence trading on the Australian Securities Exchange on 4 May 2017. New shares will rank equally in all respects with existing ordinary shares.

The capital raising was conducted at an offer price of A\$0.93 per share, representing a 14.8% premium to the last traded share priced on 29 March 2017. The capital raising was significantly oversubscribed with strong demand from new and existing shareholders, including international and domestic healthcare dedicated investment funds from Australia, United States and United Kingdom. Wilson’s Corporate Finance acted as lead manager for the offering.

“The strong support we received for this transaction follows the reporting of positive data from our Phase 1/2A clinical trial with OPT-302 in wet AMD patients, which exceeded our expectations. We are now well capitalized into 2021 which positions us to advance this next generation treatment to multiple clinical inflection points,” commented Dr Megan Baldwin, CEO and Managing Director.

Outcomes from the Phase 1/2A clinical trial demonstrated safety of intravitreally administered OPT-302, as well as improvements in visual acuity and reductions in retinal fluid in all patient groups investigated, suggesting additional clinical benefit with more complete suppression of VEGF-A and VEGF-C/D. On the basis of this data, Opthea is now actively progressing plans to initiate an approximately 350 patient Phase 2B wet AMD clinical trial, as well as additional Phase 2A clinical studies in DME and wet AMD patients who have been previously treated with anti-VEGF-A therapy and experienced a sub-optimal clinical response. Opthea plans to initiate patient recruitment into the Phase 2B wet AMD and Phase 2A clinical trials in 2H 2017.

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About Opthea Limited

Opthea (ASX:OPT) is a biologics drug developer focusing on ophthalmic disease therapies. It controls exclusive worldwide rights to a significant intellectual property portfolio around Vascular Endothelial Growth Factor (VEGF)-C, VEGF-D and VEGFR-3. The applications for the VEGF technology, which functions in regulating blood and lymphatic vessel growth, are substantial and broad. Opthea's product development programs are focused on developing OPT-302 (formerly VGX-300, soluble VEGFR-3) for 'back of the eye' disease such as wet age-related macular degeneration (wet AMD).

About the Phase 1/2A study of OPT-302 for Wet AMD

The Phase 1/2A trial recruited a total of 51 patients with wet AMD, who were either treatment naïve (n=25) or previously treated with prior intravitreal anti-VEGF-A therapy (n=26). Mean best corrected visual acuity (VA) was 59.4 letters at baseline. The study recruited a high proportion of heavily pre-treated patients (51%) and occult wet AMD lesions (73%) which are considered to be more difficult to treat with existing standard of care therapies.

The study had two parts: a sequential dose escalation (Phase 1) and a randomised dose expansion study (Phase 2A). The Phase 1 enrolled 20 patients into three ascending OPT-302 dose level cohorts (0.3, 1 and 2 mg) in combination with Lucentis® (0.5 mg), and an OPT-302 monotherapy group (2 mg). In the Phase 2A dose expansion, 31 subjects were randomised in a 3:1 ratio to two treatment cohorts with OPT-302 at 2 mg, either in combination with Lucentis® (n=23) or as monotherapy (n=8). Patients received three intravitreal injections of OPT-302 either alone or in combination with Lucentis® at 4 week intervals with a follow-up visit at week 12. For patients receiving OPT-302 monotherapy, Lucentis® rescue therapy was provided at investigator discretion or if there was a ≥ 5 letter decrease in VA and no reduction in central subfield thickness (CST) of at least 10% with presence of fluid.

About Wet AMD

Wet (neovascular) age-related macular degeneration, or wet AMD, is a disease characterised by the loss of vision of the middle of the visual field caused by degeneration of the central portion of the retina (the macula). Abnormal growth of blood vessels below the retina, and the leakage of fluid and protein from the vessels, causes retinal degeneration and leads to severe and rapid loss of vision.

Wet AMD is the leading cause of blindness in the developed world in individuals aged 50 years or older. The prevalence of AMD is increasing annually as the population ages. Without treatment, wet AMD patients often experience a chronic, rapid decline in visual acuity and increase in retinal fluid. Sales of the drug Lucentis® (Roche/Novartis), which targets VEGF-A but not VEGF-C or VEGF-D, were over \$US3.2BN in 2016. Sales of EYLEA® (Regeneron/Bayer), which also targets VEGF-A but not VEGF-C/-D first marketed in November 2011 for the treatment of wet AMD, were over \$US5.4BN in 2016. Approximately half of the people receiving Lucentis®/EYLEA® are classified as non-responders or 'poor' responders and do not experience a significant gain in vision and/or have persistent retinal vascular leakage. There is great opportunity to improve patient responses by targeting more than one factor involved in disease progression. Existing therapies, such as Lucentis® and EYLEA®, target VEGF-A that promotes blood vessel growth and leakage through its receptor VEGFR-2. VEGF-C can also induce angiogenesis and vessel leakage through the same receptor as well as through an independent pathway. Combined inhibition of VEGF-A and VEGF-C/-D, has the potential to improve patient response by more effective inhibition of the pathways involved in disease progression.

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 commercialisation 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. Thus investment in companies specialising 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 ASX announcement may contain forward-looking statements regarding Company business and the therapeutic and commercial potential of its technologies and products in development. Any statement describing Company goals, expectations, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those risks or uncertainties inherent in the process of developing technology and in the process of discovering, developing and commercialising drugs that can be proven to be safe and effective for use as human therapeutics, and in the endeavour of building a business around such products and services. Opthea undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Actual results could differ materially from those discussed in this ASX announcement.