



ASX and Media Release
28 November 2016

Opthea Chairman's Address to the 2016 AGM

Melbourne, Australia, November 28 2016 – Opthea Limited (ASX:OPT)

This is my first AGM as your Chairman and the first year that the company has operated under the name Opthea Limited and the ASX ticker OPT.

I am pleased to report on a year of significant achievements for the company. We continue to execute our plans to develop our novel therapeutic OPT-302 to treat patients with wet age-related macular degeneration (wet AMD). Approved treatments for wet AMD currently on the market have annual sales of around US\$7 billion. Despite this there's still a large unmet medical need: many patients either don't respond to these treatments or continue to deteriorate over time.

Opthea's Phase 1/2A clinical trial was initiated in July 2015 following US Food & Drug Administration (FDA) approval of our Investigational New Drug (IND) application. In just over 12 months we have reported primary and secondary outcomes from the Phase 1 study of 20 patients. We reported in April 2016 that the primary safety objective of the Phase 1 study had been met. OPT-302 demonstrated a safe and well tolerated profile in wet AMD patients when administered via intravitreal injection: on its own - as a monotherapy - and in combination with the VEGF-A inhibitor Lucentis®.

In July 2016 we achieved another important milestone for Opthea reporting positive data in respect of clinical activity outcomes in the Phase 1 clinical study. Evaluation of changes in visual acuity and retinal thickness in patients treated over a 3 month period with OPT-302 alone and in combination with Lucentis® indicated early evidence of clinical activity, demonstrating the potential of OPT-302 to improve outcomes for wet AMD sufferers. The early evidence of an additive benefit of OPT-302 observed in the Phase 1 study is encouraging and warrants further investigation of OPT-302 in a large randomised controlled study in wet AMD patients. Planning for the initiation of that Phase 2B clinical trial is currently underway.

Over the coming year we'll continue to progress the OPT-302 program. The Phase 2A patient cohorts in our ongoing clinical trial are now fully enrolled and we look forward to reporting clinical outcomes from the study early in 2017. This will be followed by the initiation of a larger Phase 2B wet AMD clinical trial. We'll continue to raise the profile of the Company both locally and internationally with presentation of clinical data at ophthalmology and investment meetings including involvement by our clinical advisory board.

Thank you to Opthea's CEO Megan Baldwin and her dedicated executive and management team. On their behalf I thank you for your support. We have a compelling program: it's a privilege to be part of a clinical stage company with a novel therapeutic in development for the treatment of the leading cause of blindness in older adults.

At the conclusion of the formal business of the meeting, our CEO and Managing Director, Megan Baldwin will provide a short review of development activities and milestones achieved over the previous 12 months, before updating you on the OPT-302 clinical program.

Company & Media Enquiries:

Megan Baldwin, PhD
CEO & Managing Director
Opthea Limited
Tel: +61 (0) 447 788 674
megan.baldwin@opthea.com

*Join our email database to receive
program updates:*

Tel: +61 (0) 3 9826 0399
info@opthea.com
www.opthea.com

Australia:

Rudi Michelson
Monsoon Communications
Tel: +61 (0) 3 9620 3333

U.S.A. & International:

Candice Knoll
Blueprint Life Science Group
Tel: +1 415 375 3340, Ext 4

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 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 \$US4.5BN in 2015. 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 \$US2.6BN in 2015. 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.

About OPT-302

OPT-302 is a soluble form of vascular endothelial growth factor receptor 3 (VEGFR-3) or 'Trap' molecule that blocks the activity of two proteins (VEGF-C and VEGF-D) that cause blood vessels to grow and leak. OPT-302 is currently being investigated in a Phase 1/2A clinical trial in wet AMD patients as a monotherapy and in combination with ranibizumab (Lucentis®). The trial is actively recruiting patients under an FDA approved IND at several US clinical sites. The purpose of the trial is to evaluate the safety, pharmacokinetics (PK) and pharmacodynamics of OPT-302 administered as monthly intravitreal injections for 3 months with and without Lucentis® in patients with wet age related macular degeneration (AMD). The study is being conducted in two parts: Part 1 (Phase 1) comprises an open label, sequential dose escalation that recruited 20 patients and Part 2 (Phase 2A) a randomized dose expansion that will recruit an additional ~30 patients and is aimed at further characterising the safety, pharmacokinetic profile and relationship between dose/PK and clinical activity of OPT-302 (+/- ranibizumab). Further details on the Phase 1/2A trial can be found at: www.clinicaltrials.gov, Clinical trial identifier: NCT02543229.

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.