Opthea Reports Fiscal Year 2022 Financial Results and Corporate Highlights

August 30, 2021

Secured up to US$170m in non-dilutive financing

Received commitments for well supported US$90m equity financing; closed first tranche for US$41.9 million

Expanded management team and US operations with appointment of C-Suite Executives

Elected Mr. Quinton Oswald and Dr. Susan Orr to Board of Directors

MELBOURNE, Australia, Aug. 30, 2022 (GLOBE NEWSWIRE) -- Opthea Limited (ASX:OPT; NASDAQ:OPT), a clinical stage biopharmaceutical company developing novel therapies to treat highly prevalent and progressive retinal diseases, today reported financial results for the fiscal year ended June 30, 2022 and provided an overview of recent progress.

“Over the past year, Opthea has focused on advancing our Phase 3 clinical trials investigating OPT-302 as a combination therapy for wet AMD. We have continued to recruit patients globally into both ShORe and COAST trials and expect to complete patient recruitment for both trials in mid CY2023 and to report topline data in mid CY2024,” said Dr. Megan Baldwin, CEO and Managing Director of Opthea. “We believe the strategic relationship with Launch Therapeutics and funding from leading investors Carlyle and Abingworth of up to US$170 million serve as an affirmation of the significant amount of work we have achieved to date and strengthens our strategic position to maximize the value of OPT-302.”

Corporate Highlights

- In August 2022, Opthea announced a non-dilutive financing transaction for up to US$170 million from Carlyle and its life sciences franchise Abingworth, working with their recently formed development company Launch Therapeutics (Launch Tx). The financing consists of a US$120 million commitment and an option for Launch Tx to increase funding by a further US$50 million. If OPT-302 is approved in a major market, Carlyle and Abingworth will be eligible to receive fixed success payments, as well as variable success payments of 7% on annual net sales, which collectively terminate after reaching four times the funded amount.
- In March 2022, Opthea announced the appointment of Dr. Joel Naor, M.D., as Chief Medical Officer (CMO).
- In January 2022, Ms. Judith Robertson was appointed as the Company’s first Chief Commercial Officer (CCO), after having formerly served as a non-executive member of the Opthea Board of Directors.
- Over the past 12 months, the Company further expanded its Board of Directors, which included welcoming Mr. Quinton Oswald and Dr. Susan Orr who have deep experience leading biotechnology companies and launching commercial products for the treatment of wet AMD and other ophthalmic diseases.

Fiscal Year 2022 Financial Results

As of June 30, 2022, Opthea had cash, cash equivalents and short-term investments of US$44.6 million.

Research and development expenses for the fiscal year ended June 30, 2022 were US$78.7 million, compared to US$25.9 million for the year ended June 30, 2021. The increase of US$52.8 million reflects costs associated with the Phase 3 clinical trials of OPT-302 for wet AMD. Administrative expenses for the fiscal year ended June 30, 2022 were US$17.9 million, compared to US$13.4 million for the same prior year period.

Opthea reported a net loss, including non-cash charges, of US$92.8 million or $0.26 per share for the year ended June 30, 2022. This compares to a net loss, including non-cash charges, of US$45.3 million or $0.14 per share for the comparable period in 2021.

A copy of Opthea’s financial results and Annual Report for the fiscal year ended June 30, 2022 is available on the Company’s website www.opthea.com/annual-reports/. Opthea also expects to file an Annual Report on Form 20-F with the Securities and Exchange Commission for the fiscal year ended June 30, 2022 at a later date.

About Opthea Limited

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 Opthea's goals, expectations, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement, including, but not limited to, the expected enrollment of a significant number of patients for the trials, the advancement of Opthea's Phase 3 registrational program and commercialization efforts for OPT-302, the expected timing of Opthea's Phase 3 program and trials, Opthea's anticipated funding needs and cash runway, including following financing activities such as the non-dilutive financing transaction with Launch Tx, Opthea's ability to meet its payment and other obligations under the agreement with Launch Tx, Opthea's ability to draw the entire US$170 million of funding capacity under the agreement with Launch Tx in a timely manner or at all, Opthea's ability to comply with its obligations under the agreement with Launch Tx, including minimum cash requirements, Opthea's ability to consummate the second tranche of the private placement and Opthea's goal of building out a substantial presence in the United States. 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, including unexpected costs or delays in the clinical trial process, risks from the continuing COVID-19 pandemic, 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 Opthea's Annual Report on Form 20-F filed with the SEC on October 28, 2021. If the risks materialize or assumptions prove incorrect, actual results could differ materially from the results implied by these forward-looking statements. 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.

Authorized for release to ASX by Megan Baldwin, CEO & Managing Director.

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