



ASX and NASDAQ Release
15 August 2022

Form 6-K with SEC

Melbourne, Australia; 15 August, 2022 – Opthea Limited (ASX:OPT; NASDAQ: OPT) (**Opthea**) attaches for release to ASX the contents of a report on Form 6-K that it will furnish to the United States Securities and Exchange Commission (**SEC**) on or around the date of this announcement.

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. To learn more, visit www.opthea.com.com and follow us on Twitter 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.

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 Megan Baldwin, CEO & Managing Director



Contacts:

Company & Media Enquiries:

U.S.A. & International:

Sam Martin
Argot Partners
Tel: +1 212-600-1902
opthea@argotpartners.com

Australia:

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

***Join our email database to receive
program updates:***

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

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934**

For the Month of August 2022

Commission File Number: 001-39621

OPTHEA LIMITED

(Translation of registrant's name into English)

**Level 4
650 Chapel Street
South Yarra, Victoria 3141
Australia
(Address of principal executive offices)**

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

INCORPORATION BY REFERENCE

This Report on Form 6-K (the "Report") (excluding Exhibits 99.1 and 99.2 thereto) shall be deemed to be incorporated by reference into the registration statements of Opthea Limited (the "Company") on Form S-8 (File No. 333-251052) and Form F-3 (File No. 333-262444) and to be a part thereof from the date on which this Report is filed, to the extent not superseded by documents or reports subsequently furnished.

Development Funding-Agreement with Ocelot SPV LP

On August 12, 2022 (the “Effective Date”), Opthea Limited (“Opthea”) entered into a Development Funding Agreement (the “Agreement”) with Ocelot SPV LP (“Investor”), an affiliate of Carlyle and Abingworth, working together with Carlyle and Abingworth’s recently formed development company Launch Therapeutics, pursuant to which Investor agrees to provide funding to Opthea to support its development of OPT-302 for the treatment of wet (neovascular) age-related macular degeneration (“wet AMD”).

Pursuant to the Agreement, Investor has committed to provide Opthea US\$120 million in funding which may be increased up to US\$170 million at Investor’s option, of which US\$50 million will be paid shortly after Opthea receives the proceeds from the first tranche of the PIPE (as defined below), with the remainder being funded in two additional tranches to be paid on December 31, 2022 and December 31, 2023, respectively. Pursuant to the Agreement, Opthea will be required to use commercially reasonable efforts to develop OPT-302 for the treatment of wet AMD in accordance with the Agreement, including pursuant to certain development timelines set forth therein.

In return, Opthea will pay to Investor (1) upon the first to occur of regulatory approval of OPT-302 for the treatment of wet AMD in the United States, United Kingdom or European Union (“Regulatory Approval”), fixed payments equal to a total of approximately two times the funding provided, consisting of seven payments, with the first payment due shortly after Regulatory Approval and the remaining six payments payable over a six-year period thereafter, and (2) variable payments equal to 7% of net sales of OPT-302 for the treatment of wet AMD for each calendar quarter.

At the time that Investor receives an aggregate of four times the funding provided (US\$680 million if Investor funds the full US\$170 million under the Agreement) (the “Cap”), Opthea’s payment obligations under the Agreement will be fully satisfied. Opthea has the option to satisfy its payment obligations to Investor upon Regulatory Approval or a change of control of Opthea by paying an amount equal to the present value of the remaining payments payable to Investor subject to a mid-single-digit discount rate. Opthea also has an option to buy out the remaining payments at any time by paying an amount equal to the remaining payments due subject to a proposed discount rate, which Investor may accept or reject. Upon a change of control of Opthea, an acceleration payment of a specified multiple of the funding provided is payable, net of payments already made to Investor and creditable against future payments to Investor.

Opthea will grant Investor a security interest in all of its assets (other than intellectual property not related to OPT-302). The security interest will terminate when Investor receives payments and/or change of control acceleration payments equal to two times the funding provided or upon certain terminations of the Agreement (the “Release Date”). The Agreement also includes customary representations and warranties and covenants, including certain negative covenants regarding limitations on incurrence of indebtedness, liens, investments, restricted payments, sales of assets, and royalty sales. The negative covenants will terminate upon the Release Date.

The Agreement terminates upon the payment of all payments owing to Investor, unless earlier terminated by Investor if:

- Opthea fails to comply with certain covenants and agreements set forth in the Agreement, including failure to make required payments or develop OPT-302 as set forth in the Agreement;
- Opthea suffers a material adverse event;
- there is a material adverse patent impact on Opthea’s intellectual property covering OPT-302;
- there are certain irresolvable disagreements within the joint steering committee overseeing Opthea’s development of OPT-302;
- the security interests of Opthea are invalidated or terminated other than as set forth in the Agreement; or
- any Phase 3 clinical trial of OPT-302 is completed or terminated and (1) the primary endpoint is not met or (2) Investor reasonably determines that the results of any such trial do not support regulatory approval.

The Agreement may also be earlier terminated by Opthea if Investor fails to fund as provided in the Agreement. The Agreement may be terminated by either party (i) if the other party materially breaches the Agreement (“Material Breach”), (ii) if OPT-302 fails to receive regulatory approval in the United States or European Union, (iii) upon the bankruptcy of the other party, (iv) if a serious safety concern arises in an OPT-302 clinical trial or (v) upon a change of control of Opthea.

In certain instances, upon the termination of the Agreement, Opthea will be obligated to pay Investor a multiple of the amounts paid to Opthea under the Agreement, including specifically,

- up to the Cap in the event that Investor terminates the agreement due to (w) failure by Opthea to comply with certain covenants and agreements set forth in the Agreement, including failure to make required payments or develop OPT-302 as set forth in the Agreement, (x) the bankruptcy of Opthea, (y) a safety concern resulting from gross negligence on the part of Opthea or due to a safety concern that was material on the Effective Date and the material data showing such safety concern was not publicly known, disclosed to Investor, or in the diligence room made available to Investor or (z) the security interests of Investor being invalidated or terminated other than as set forth in the Agreement;
- several multiples of such amounts in the event the Agreement is terminated due to Material Breach by Opthea; and
- a small multiple of such amounts in the event of certain irresolvable disagreements within the executive review committee overseeing Opthea’s development of OPT-302.

In addition, if following certain events of termination of the Agreement, Opthea continues to develop OPT-302 for the treatment of wet AMD and obtains Regulatory Approval, it will make the payments to Investor as if the Agreement had not been terminated, less any payments made upon termination.

The Agreement also provides that Opthea will use reasonable best efforts to complete a private placement of its ordinary shares or American Depositary Shares (“ADSs”) representing its ordinary shares (at a ratio of 8 ordinary shares per ADS) for gross proceeds of at least US\$70 million, which Opthea expects will be satisfied through the PIPE (as described below under “PIPE Financing”).

The Agreement also includes a minimum cash requirement, and Opthea may need to obtain additional funding to meet this requirement in the future, including prior to the expected readout of top-line results for its Phase 3 clinical trials. To the extent that Opthea raises additional capital through the sale of equity or convertible debt securities to meet this requirement, Opthea’s equity holders will be diluted.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by the full text of the Agreement, a copy of which will be filed as an exhibit to Opthea’s Annual Report on Form 20-F for the fiscal year ended June 30, 2022, which will be subsequently filed with the Securities and Exchange Commission.

PIPE Financing

Concurrently with the execution of the Agreement, Opthea entered into binding commitments for the private placement of ordinary shares to be issued pursuant to Regulation S under, and Section 4(a)(2) of, the Securities Act of 1933, as amended (the “Securities Act”), as the case may be, for aggregate gross proceeds of approximately US\$90 million (the “PIPE”) and a price per ordinary share of A\$1.15 (approximately US\$0.81).

The PIPE consists of two tranches. The first tranche will be for US\$42.5 million, or 52.8 million ordinary shares, which amount represents the amount of new ordinary shares that Opthea may currently issue without obtaining shareholder approval under ASX Listing Rules. The first tranche is expected to be consummated on or about August 24, 2022. Opthea will use reasonable best efforts to obtain shareholder approval to issue and consummate the second tranche, which will be for US\$47.5 million, or 59 million shares.

Opthea expects to issue a Notice of Meeting to its shareholders to convene a general meeting of shareholders expected in September 2022 to obtain shareholder approval to issue and consummate the second tranche.

Operational Update

Opthea expects to use the net proceeds from the Agreement and the PIPE (the “Transactions”), together with its existing cash and cash equivalents, to continue advancing the clinical development of OPT-302 for the treatment of wet AMD, including the Phase 3 clinical trials, and anticipates that any remaining proceeds will fund pre-commercialization activities, including commercial scale manufacturing, team build and market shaping, as well as for working capital and general corporate purposes. Opthea believes its current cash and cash equivalents, together with the net proceeds from the Transactions, will be sufficient to fund its operations and research and development expenses through at least the fourth calendar quarter of 2024. Opthea continues to expect to complete patient recruitment in the Phase 3 clinical trials of OPT-302 for the treatment of wet AMD by mid-2023, with topline data to be reported when all patients complete the 52-week treatment period for the primary analysis. If the topline results at the completion of the primary efficacy phase are favorable, Opthea expects to file for marketing approval for OPT-302 for the treatment of wet AMD in the United States, European Union and other territories.

The amounts and timing of Opthea’s expenditures will depend upon and have been impacted in the past, and may continue to be impacted by, numerous factors, including the results of its research and development efforts, the timing and success of ongoing clinical trials or clinical trials that Opthea may commence in the future, the timing of regulatory submissions, the performance and cost efficiency of third parties that assist Opthea with clinical development, including clinical research organizations (“CROs”), and the continuing impacts of the COVID-19 pandemic and macroeconomic challenges. As previously disclosed, Opthea’s efforts to advance its Phase 3 clinical trials, including clinical trial activations and trial site engagements, have been challenged in part by the COVID-19 pandemic and administrative delays. In particular, Opthea has incurred and experienced, and may continue to incur and experience in the future, significantly increased costs and delays in connection with the activities conducted by third-party CROs and other third parties to prepare for and progress Opthea’s Phase 3 clinical trials.

Opthea has based its beliefs and expectations stated above on assumptions that may prove to be wrong, including due to the continued uncertainty relating to the COVID-19 pandemic and related macroeconomic challenges. Opthea may also experience future delays in its clinical development or commercialization of OPT-302 for any indication, including due to the factors and conditions set forth above or other factors that Opthea cannot presently anticipate, and may use its available capital resources sooner than Opthea currently expects. Following this Transaction, Opthea will require additional funding to reach commercialization of OPT-302 in any indication, including wet AMD.

Forward-looking Statements

Certain statements in this report may contain forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statement describing Opthea’s goals, expectations, estimates, 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 pursuant to the Agreement and the PIPE as well as to maintain compliance with the minimum cash requirement under the Agreement, Opthea’s ability to meet its payment and other obligations under the Agreement, including compliance with the minimum cash requirement, Opthea’s ability to draw the entire US\$170 million of funding capacity under the Agreement in a timely manner or at all, Opthea’s ability to consummate the second tranche of the PIPE, 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. Opthea 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 in this report.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: August 15, 2022

OPTHEA LIMITED

By: /s/ Megan Baldwin

Megan Baldwin, Ph.D.

Chief Executive Officer and Managing Director