



DIVISION OF
CORPORATION FINANCE

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

August 13, 2020

Megan Baldwin, Ph.D.
Chief Executive Officer and Managing Director
Opthea Limited
Level 4
650 Chapel Street
South Yarra, Victoria 3141
Australia

Re: Opthea Limited
Draft Registration Statement on Form F-1
Submitted July 17, 2020
CIK No. 0001815620

Dear Dr. Baldwin:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form F-1 submitted July 17, 2020

COVER PAGE

1. We note your disclosure that the last reported sale price of your ordinary shares on the Australian Securities Exchange was A\$ _____ per ordinary share and that the final offering price will be determined through negotiations with the underwriters and will take into account market conditions and other factors. However, your statements on page 187 indicate that your underwriters propose to offer the shares at the price set forth on the cover page. Please revise your cover page to provide a bona fide range for the ADSs, or alternatively, you may use the most recent home market trading price, converted to US

dollars at the most recent exchange rate, if the U.S. IPO price will be substantially similar to the home market trading price.

2. Please revise your third paragraph to disclose that there is currently no established public trading market in the U.S. for the offered securities.

PROSPECTUS SUMMARY

Overview, page 1

3. Please revise to limit the discussion of clinical trial results in your prospectus summary to the endpoints of the trial and whether they were met. Also balance your disclosure by adding a discussion of serious adverse events, which you discuss in the Business section, and that you do not have any data for OPT-302 for longer than 24 weeks.
4. We note your statement that there is a significant and expanding market opportunity in wet AMD. Please quantify the current market size. It is not clear from the disclosure whether the current market size is equal to the worldwide sales of ranibizumab and aflibercept or some other figure.
5. The pipeline tables on pages 3 and 97 appears to present two separate programs for Wet AMD. Please remove the second arrow, otherwise revise to clarify, or advise.

Implications of Being an Emerging Growth Company, page 5

6. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

RISK FACTORS

We have received tax incentives under the Research and Development Tax Incentive scheme in Australia. . . , page 35

7. Revise to quantify the amount of cash incentives at issue.

As a foreign private issuer, we are permitted to adopt certain home country practices..., page 66

8. We note your disclosure on page 66 and throughout the prospectus that you intend to follow home country corporate governance practices. Please revise to provide a concise summary of all material differences between corporate governance practices in Australia and required by Nasdaq for domestic companies.

USE OF PROCEEDS, page 72

9. Please revise to identify the stage of development you expect to achieve for your product candidate in the wet AMD indication with the proceeds of the offering. If the anticipated proceeds will not be sufficient to fund all the proposed purposes, please disclose the order

of priority of such purposes. To the extent material amounts of other funds are necessary to accomplish the specified purposes, state the amounts and sources of such other funds needed for each specified purpose. Refer to Item 3.C.1 of Form 20-F.

10. To the extent that a material amount of proceeds remain after the allocation to OPT-302 for wet AMD, please revise your disclosure to include the estimated amount of proceeds you plan to allocate for each of the uses identified in the second bullet point.

BUSINESS

Phase 1/2a Clinical Trial Results in Wet AMD, page 103

11. We refer to the comparison in the second full paragraph on page 104 of your Phase 1/2a data to historical results from the pivotal Phase 3 ranibizumab monotherapy trial. Please remove this comparison as it is not based on a head-to-head study. We note that your discussion of your Phase 2b results includes a comparison of the results from the 2.0 mg OPT-302 combination therapy group with those from the ranibizumab monotherapy group.

Phase 2b Clinical Trial Results in Wet AMD, page 105

12. Please provide a textual discussion of the statistical analysis performed on the data presented on pages 107-114. Also add an explanation of how statistical significance relates to the approval process of the FDA and other regulators.
13. Please revise the first sentence of the penultimate paragraph on page 113 to explain the significance of these observations.

Phase 2a Clinical Trial of OPT-302 in DME, page 118

14. We refer to your statement on page 122 that you have extensive dosing experience demonstrating a "favorable safety profile." Safety determinations are within the authority of the FDA and comparable regulatory authorities, and such statements are not appropriate. Please revise to remove this statement.

Board of Directors, page 144

15. Please clarify the paragraph on page 144 to explain, if true, that retiring directors are eligible for re-election.

MANAGEMENT

Employment Agreements with Senior Management, page 150

16. Please file your employment agreements with each of your executive officers as exhibits to the registration statement. See Instruction 4 to Exhibits on Form 20-F.

Megan Baldwin, Ph.D.
Opthea Limited
August 13, 2020
Page 4

PRINCIPAL SHAREHOLDERS, page 155

17. Please identify the natural persons who are the beneficial owners of the shares held by the 5% or greater shareholders identified in your table.

DESCRIPTION OF AMERICAN DEPOSITARY SHARES

Governing Law/Waiver of Jury Trial, page 173

18. We note your disclosure regarding the waiver of jury trial provision on page 173. Please include a risk factor to highlight the material risks related to this provision, including the possibility of less favorable outcomes, uncertainty regarding its enforceability, the potential for increased costs to bring a claim, whether it may discourage or limit suits against you or the depositary and whether the provision applies to purchasers in secondary transactions. Also disclose whether this provision would apply if the ADS holder were to withdraw the ordinary shares.

You may contact Nudrat Salik at 202-551-3692 or Brian Cascio at 202-551-3676 if you have questions regarding comments on the financial statements and related matters. Please contact Jeffrey Gabor at 202-551-2544 or Dorrie Yale at 202-551-8776 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Ferish Patel, Esq.