

**16 February 2023**

**By email**

Melissa Kostopoulos  
Adviser, Listings Compliance (Melbourne)  
Level 4, North Tower, Rialto  
525 Collins Street, Melbourne VIC 3000

Dear Melissa

**Opthea Limited - Response to ASX Query Letter**

We refer to your letter dated 14 February 2023, with subject line “Opthea Limited (‘OPT’): Query Letter” (**Letter**) which requested certain information to be provided by Opthea Limited (**Opthea**).

Please see the responses of Opthea to the queries raised in your Letter set out below. Capitalised terms used in this letter have the meaning given in your Letter unless the context otherwise requires.

We adopt the same numbering of the queries set out in your Letter.

1. No, Opthea does not consider the contents of the Announcement to be information that a reasonable person would expect to have a material effect on the price or value of its securities.

We note that there was, in fact, no material effect on the price or value of Opthea’s securities after the release of the Announcement.

2. Not applicable.

- 3.

- 3.1. As noted in your Letter, the Article was published online in a public, open access, forum on the American Academy of Ophthalmology website on 5 February 2023.

The Article contains a peer reviewed manuscript describing the results of Opthea’s Phase 2b study, which, as you have noted, have previously been fully disclosed by Opthea on MAP, including on 6 September 2019 “*Opthea Presents Positive Data from OPT-302 Phase 2b Wet AMD Trial at EURETINA Congress*” and on 11 October 2019 “*Opthea Presents Additional Data from OPT-302 Phase 2b Wet AMD Trial at the Ophthalmology Innovation Summit in San Francisco*”.

Opthea considered that, while a reasonable person would not have expected the information in Article to have a material effect on the price or value of its securities (given the results of the Phase 2b study have been previously released to the market), investors would nonetheless be interested in the results of the peer review and Opthea’s views on that peer review.

Opthea’s review of the Article (and preparation of the announcement with confirmation of the quote contained in the Announcement from the lead author of the Article) was not finalised until approximately one week after the Article’s published date (particularly due to global time differences) and, once finalised, lodged with MAP (as well as the United States’ SEC).

We note that informing the market of the publication of such commentary is consistent with previous practice of Opthea. Previously, on 29 October 2019, Opthea released a similar

announcement “*Opthea First-in-Human Clinical Data for OPT-320 in wet AMD Published in Leading Ophthalmic Journal*” which was published on 23 October 2019.

- 3.2. Opthea considers the Announcement to be in compliance with ASX’s guidance against ramping.

The Announcement is purely factual and informs the market that the peer review of the outcomes of the Phase 2b study (which was previously released on the MAP and based on which its current Phase 3 studies are being conducted) had been published in the Article, and informed the market where that Article could be accessed if any investors wished to read it. This is substantive information. There is no exuberant or promotional language in the Announcement.

The basis of the Announcement was to ensure the market was informed and aware that the peer reviewed Article has been published and where investors could access that Article if they were interested to do so. It was not to “ramp up” the share price of its securities.

Indeed, Opthea’s share price at close of trade on 14 February 2023 was \$0.905 (i.e. closed down \$0.030 from the closing price on 13 February 2023 (prior to the Announcement being lodged on MAP)). There was no material impact on the price or value of Opthea’s securities following the Announcement.

- (a) The Announcement did not contain material information (being information a reasonably person would expect to have a material impact on the price or value of Opthea’s securities) that has not previously been disclosed on MAP or other public sources (as noted above, the results of Phase 2b have been in the market for some time now). However, it did inform the market that the peer review Article had been published, which, as stated above, Opthea understood investors would be interested in.
- (b) While the announcement did not contain new and material information (being information a reasonably person would expect to have a material impact on the price or value of Opthea’s securities) it did contain new information being that the data had undergone peer review, was accepted for publication and the Article had been published.
4. Opthea confirms that it is complying with the Listing Rules and, in particular, Listing Rule 3.1.
5. Authorized for release to ASX by Megan Baldwin, CEO & Managing Director.

Yours sincerely



**Karen Adams**  
**Vice President Finance and Company Secretary**  
**Opthea Limited**



14 February 2023

Reference: 68160

Ms Karen Adams  
Company Secretary  
Opthea Limited  
Suite 0403, Level 4  
650 Chapel Street  
South Yarra 3141

By email: karen.adams@opthea.com

Dear Ms Adams

### **Opthea Limited ('OPT'): Query Letter**

ASX refers to the following:

- A. OPT's announcement titled "Opthea Phase 2b Trial Results of OPT-302 in Combination with Lucentis® for wet AMD Published in the Journal Ophthalmology", marked "market sensitive" and released on the ASX Market Announcements Platform ('MAP') on 14 February 2023 (the 'Announcement').

The Announcement disclosed that the results of the Phase 2b study of OPT-302 was published in an article titled "A randomized controlled trial of OPT-302, a VEGFC/D inhibitor for neovascular age-related macular degeneration" in the Ophthalmology journal (the 'Article').

- B. The American Academy of Ophthalmology website, which disclosed that the Article was published online on 5 February 2023 on an open access basis.<sup>1</sup>
- C. OPT's disclosures on MAP disclosing details of the Phase 2b study results. Particularly, OPT's presentation titled "Opthea Corporate Presentation – San Francisco Jan 2023" and released on MAP on 11 January 2023, which disclosed detailed results from the Phase 2b study from slides 11 to 21.

#### Listing Rules

- D. Listing Rule 3.1, which requires a listed entity to immediately give ASX any information concerning it that a reasonable person would expect to have a material effect on the price or value of the entity's securities.

- E. The definition of "aware" in Chapter 19 of the Listing Rules, which states that:

*"an entity becomes aware of information if, and as soon as, an officer of the entity (or, in the case of a trust, an officer of the responsible entity) has, or ought reasonably to have, come into possession of the information in the course of the performance of their duties as an officer of that entity" and section 4.4 in Guidance Note 8 Continuous Disclosure: Listing Rules 3.1 – 3.1B "When does an entity become aware of information."*

- F. Section 4.15 of Guidance Note 8 Continuous Disclosure which states:

*"Wherever possible, an announcement under Listing Rule 3.1 should contain sufficient detail for investors or their professional advisers to understand its ramifications and to assess its impact on the price or value of the entity's securities..."*

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<sup>1</sup> [https://www.aaojournal.org/article/S0161-6420\(23\)00066-0/fulltext](https://www.aaojournal.org/article/S0161-6420(23)00066-0/fulltext)

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*Entities should not use an announcement under Listing Rule 3.1 as a guise to publish material that is really promotional, political or tendentious in nature rather than being information that a reasonable person would expect to have a material effect on the price or value of the securities."*

G. Section 7.10 of Guidance Note 8 *Continuous Disclosure* which states:

*"ASX is alive to listed entities making market announcements with a view to "ramping up" the price of their securities. Ramping announcements come in many forms, including:*

- *the release of a "business update" or something similar, which will typically be worded in an exuberant fashion but which on close examination contains little in the way of substance..."*

### **Request for information**

Having regard to the above, ASX asks OPT to respond separately to each of the following questions and requests for information:

1. Does OPT consider the contents of the Announcement to be information that a reasonable person would expect to have a material effect on the price or value of OPT's securities?
2. If the answer to Question 1 is "yes":
  - 2.1 Please identify the new and material information, not previously disclosed on MAP, in the Announcement that a reasonable person would expect to have a material impact on the price or value of OPT's securities.
  - 2.2 Please identify the detail in the Announcement that would allow investors or their professional advisers to understand its ramifications and assess its impact on the price or value of OPT's securities, given the information already available on MAP (paragraph F).
  - 2.3 When did OPT become aware of the information identified above in Question 2.1 (paragraph E)?
  - 2.4 Does OPT consider the contents and timing of the release on the Announcement to be in compliance with its obligations under the Listing Rules? Please provide the basis for this view.
3. If the answer to Question 1 is "no":
  - 3.1 Please explain the basis for lodging the Announcement on MAP.
  - 3.2 Does OPT consider the Announcement to be in compliance with ASX's guidance against ramping (paragraph G)? In responding to this question please comment specifically on:
    - (a) The new and material information available identified in the Announcement that was not previously available on MAP or other public sources; and
    - (b) How the new and material information would assist investors or their professional advisers in assessing the price or value of OPT's securities (paragraph F).
4. Please confirm that OPT is complying with the Listing Rules and, in particular, Listing Rule 3.1.
5. Please confirm that OPT's responses to the questions above have been authorised and approved in accordance with its published continuous disclosure policy or otherwise by its board or an officer of OPT with delegated authority from the board to respond to ASX on disclosure matters.

### **When and where to send your response**

This request is made under Listing Rule 18.7. Your response is required as soon as reasonably possible and, in any event, by no later than **9:30 AM AEDT Friday, 17 February 2023**. You should note that if the information

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requested by this letter is information required to be given to ASX under Listing Rule 3.1 and it does not fall within the exceptions mentioned in Listing Rule 3.1A, OPT's obligation is to disclose the information 'immediately'. This may require the information to be disclosed before the deadline set out in the previous paragraph and may require OPT to request a trading halt immediately.

Your response should be sent to me by e-mail at [ListingsComplianceMelbourne@asx.com.au](mailto:ListingsComplianceMelbourne@asx.com.au). It should not be sent directly to the ASX Market Announcements Office. This is to allow me to review your response to confirm that it is in a form appropriate for release to the market, before it is published on the ASX Market Announcements Platform.

### **Trading halt**

If you are unable to respond to this letter by the time specified above, you should discuss with us whether it is appropriate to request a trading halt in OPT's securities under Listing Rule 17.1. If you wish a trading halt, you must tell us:

- the reasons for the trading halt;
- how long you want the trading halt to last;
- the event you expect to happen that will end the trading halt;
- that you are not aware of any reason why the trading halt should not be granted; and
- any other information necessary to inform the market about the trading halt, or that we ask for.

We require the request for a trading halt to be in writing. The trading halt cannot extend past the commencement of normal trading on the second day after the day on which it is granted. You can find further information about trading halts in Guidance Note 16 *Trading Halts & Voluntary Suspensions*.

### **Suspension**

If you are unable to respond to this letter by the time specified above, ASX will likely suspend trading in OPT's securities under Listing Rule 17.3.

### **Listing Rules 3.1 and 3.1A**

In responding to this letter, you should have regard to OPT's obligations under Listing Rules 3.1 and 3.1A and also to Guidance Note 8 *Continuous Disclosure: Listing Rules 3.1 – 3.1B*. It should be noted that OPT's obligation to disclose information under Listing Rule 3.1 is not confined to, nor is it necessarily satisfied by, answering the questions set out in this letter.

### **Release of correspondence between ASX and entity**

We reserve the right to release a copy of this letter, your reply and any other related correspondence between us to the market under Listing Rule 18.7A.

### **Questions**

If you have any questions in relation to the above, please do not hesitate to contact me.

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Yours sincerely

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**Melissa Kostopoulos**  
Adviser, Listings Compliance (Melbourne)