



13 February 2025

ASX Listings Compliance
ASX Limited
20 Bridge Street
SYDNEY NSW 2000

By email: ListingsComplianceSydney@asx.com.au

Clarity Pharmaceuticals Ltd (CU6): Cleansing Notice Timing

Clarity Pharmaceuticals Ltd (“**Clarity**” or “**Company**”) refers to your letter dated 10 February 2025 (**ASX Letter**). Unless otherwise defined, any capitalised terms in this letter are as defined in the ASX Letter.

In response to the ASX Letter, Clarity provides the following responses:

- 1. Does CU6 consider the information disclosed in the Announcement and set out in Paragraph B above, or any part thereof, to be information that investors and their professional advisers would reasonably require for the purpose of making an informed assessment of either:**
 - 1.1 the assets and liabilities, financial position and performance, profits and losses and prospects of CU6; or**
 - 1.2 the rights and liabilities attaching to the relevant securities?**

No.

- 2. If the answer to either limb of question 1 is “no”, please advise the basis for that view.**

The Company notes that on 22 August 2024, it announced that the U.S. Food and Drug Administration (**FDA**) had granted Fast Track Designation (**FTD**) for 64Cu-SAR-bisPSMA for positron emission tomography (**PET**) imaging of prostate-specific membrane antigen (**PSMA**) positive prostate cancer lesions with suspected metastasis who are candidates for initial definitive therapy (**2024 Announcement**).

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The Announcement is an update to the 2024 Announcement, and builds on, and provides further information to the 2024 Announcement.

The Company is of the view that:

- it is appropriate for maintaining an informed market to provide an update to the FTD of the 64Cu-SAR-bisPSMA for PET imaging as described in the Announcement; and
- an absence of the information in the Announcement would not prevent investors and their professional advisers from making an informed assessment of either:
 - the assets and liabilities, financial position and performance, profits and losses and prospects of CU6; or
 - the rights and liabilities attaching to the relevant securities.

This view is on the basis that the market has an expectation that the Company will provide timely updates on achievement of such milestones, however the designation, does not materially change the assets and liabilities, financial position and performance, profits and losses and prospects of the Company, or the rights and liabilities attaching to the relevant securities.

The Company notes that although the FTD indicates that the FDA is supportive of the Company's product application, the Company must still successfully complete, amongst other things, the Phase 3 Clinical Trial, the outcome of which will not be known until the trial is completed and regulatory approval granted.

In addition, the Company notes that the Announcement was released at 9.40am on 24 January 2025. The Company's share price as at close on 23 January 2025 was \$4.06. Following release of the Announcement, the Company's share price increased \$0.04 (0.99%) during the course of trading on the day of the release (24 January 2025) and closed on 24 January 2025 at \$4.10 (an increase of 0.99%).

The Company notes the guidance provided in ASX Listing Rules Guidance Note 8 regarding the actual effect that information had on the market price of the entity's securities when it was announced to the market, specifically the materiality guidelines that formerly appeared in the Australian Accounting standards as a reasonable measure of materiality (5%/10%).

3. Does CU6 consider the Announcement to include information for which it is reasonable for investors and their professional advisers to expect to find in a disclosure document?

No.

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4. If the answer to question 3 is “no”, please advise the basis for that view.

For the reasons outlined in the Company’s response to question 2, the Company provided the information in the Announcement by way of update and the information updates the information previously disclosed by the Company in the 2024 Announcement.

The information provided in the Announcement demonstrates that the FDA continues to be supportive of the Company's new drug application and the need to assist in prioritising the application as it makes its way through the approval process; however, the outcome of this process is still dependent on the progress and success of the clinical trial (which is uncertain at this stage).

5. If the answer to question 3 is “yes”, please detail the information.

N/A.

6. If the answer to either limb in question 1 is “yes”, please specify the date and time when CU6 first became aware of the relevant information in the Announcement.

N/A.

7. If CU6 first became aware of the relevant information before lodging the Cleansing Notice on MAP, was CU6 relying on the provisions of Listing Rule 3.1A not to release the information before CU6 lodged the Announcement on MAP?

The Company does not consider the information contained in the Announcement to be information that a reasonable person would expect to have a material effect on the price or value of its securities. Accordingly, the Company was not relying on the provisions of Listing Rule 3.1A in not releasing the information before the Company lodged the Announcement on MAP.

The Company acknowledges that the Announcement was submitted by the Company as “market sensitive” when it was lodged on MAP. The Company indicated that the Announcement was “market sensitive” consistent with the approach taken previously when the 2024 Announcement was lodged with MAP and taking a cautious approach. However, on reflection, especially given the lack of share price movement following release of the Announcement, the Company acknowledges the Announcement was not market sensitive.

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8. **If CU6 first became aware of the information prior to the lodging of the Cleansing Notice on MAP, please explain why the information was not set out in the Cleansing Notice pursuant to the Act?**

Prior to lodging the Cleansing Notice on MAP, the Company Secretary sought confirmation in accordance with the Company's usual practice that the Company could issue the cleansing notice. The Company does not consider the information contained in the Announcement to be "excluded information" for the purposes of section 708A of the Corporations Act.

9. **Please confirm that CU6 is in compliance with the Listing Rules and, in particular, Listing Rule 3.1.**

Clarity confirms that it is in compliance with the Listing Rules and, in particular, Listing Rule 3.1.

10. **Please confirm that CU6'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 CU6 with delegated authority from the board to respond to ASX on disclosure matters.**

The above responses are authorised and approved by the Executive Chairman.

Yours sincerely

A handwritten signature in black ink, appearing to read "R. Vickery", written in a cursive style.

Robert Vickery
Company Secretary

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10 February 2025

Reference: 105966

Mr Robert Vickery
Company Secretary
Clarity Pharmaceuticals Ltd
'National Innovation Centre'
Suite 212a 2-4 Cornwallis Street
EVELEIGH NSW 2015

By email

Dear Mr Vickery

Clarity Pharmaceuticals Ltd ('CU6'): Cleansing Notice Timing

ASX refers to the following:

- A. CU6's announcement titled 'Cleansing Notice' released on the ASX Market Announcements Platform ('MAP') at 3:46 PM on 22 January 2025 (the 'Cleansing Notice'), disclosing amongst other things:

"... (c) as at the date of this notice, Clarity has complied with:

- (i) the provisions of Chapter 2M Corporations Act as they apply to Clarity; and*
- (ii) sections 674 and 674A Corporations Act; and*

(d) as at the date of this notice, there is no excluded information of the type referred to in sections 708A(7) and 708A(8) Corporations Act to be disclosed under section 708A(6)(e) Corporations Act."

- B. CU6's announcement titled 'Clarity receives U.S. FDA Fast Track Designation' released on MAP at 9:40 AM on 24 January 2025 (the 'Announcement') disclosing the following:

"... the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation (FTD) for 64Cu-SAR-bisPSMA for positron emission tomography (PET) imaging of prostate-specific membrane antigen (PSMA) positive prostate cancer lesions in patients with biochemical recurrence (BCR) of prostate cancer following definitive therapy."

- C. Section 708A(7) of the Corporations Act 2001 (Cth) (the 'Act') which states:

'For the purposes of subsection (6), excluded information is information:

- (a) that has been excluded from a continuous disclosure notice in accordance with the listing rules of the relevant market operator to whom that notice is required to be given; and*
- (b) that investors and their professional advisers would reasonably require for the purpose of making an informed assessment of:*
 - (i) the assets and liabilities, financial position and performance, profits and losses and prospects of the body; or*
 - (ii) the rights and liabilities attaching to the relevant securities.'*

- D. The definition of 'aware' in Chapter 19 of the Listing Rules. This definition 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.'

Additionally, you should refer to section 4.4 in Guidance Note 8 *Continuous Disclosure*: Listing Rules 3.1 – 3.1B 'When does an entity become aware of information?'

- E. Listing Rule 3.1A, which sets out exceptions from the requirement to make immediate disclosure, provided that each of the following are satisfied.

'3.1A Listing rule 3.1 does not apply to particular information while each of the following is satisfied in relation to the information:

3.1A.1 One or more of the following 5 situations applies:

- It would be a breach of a law to disclose the information;*
- The information concerns an incomplete proposal or negotiation;*
- The information comprises matters of supposition or is insufficiently definite to warrant disclosure;*
- The information is generated for the internal management purposes of the entity; or*
- The information is a trade secret; and*

3.1A.2 The information is confidential and ASX has not formed the view that the information has ceased to be confidential; and

3.1A.3 A reasonable person would not expect the information to be disclosed.'

Request for information

Having regard to the above, ASX asks CU6 to respond separately to each of the following questions.

1. Does CU6 consider the information disclosed in the Announcement and set out in Paragraph B above, or any part thereof, to be information that investors and their professional advisers would reasonably require for the purpose of making an informed assessment of either:
 - 1.1 the assets and liabilities, financial position and performance, profits and losses and prospects of CU6;
or
 - 1.2 the rights and liabilities attaching to the relevant securities?
2. If the answer to either limb of question 1 is "no", please advise the basis for that view.
3. Does CU6 consider the Announcement to include information for which it is reasonable for investors and their professional advisers to expect to find in a disclosure document?
4. If the answer to question 3 is "no", please advise the basis for that view.
5. If the answer to question 3 is "yes", please detail the information.
6. If the answer to either limb in question 1 is "yes", please specify the date and time when CU6 first became aware of the relevant information in the Announcement.

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7. If CU6 first became aware of the relevant information before lodging the Cleansing Notice on MAP, was CU6 relying on the provisions of Listing Rule 3.1A not to release the information before CU6 lodged the Announcement on MAP?
 8. If CU6 first became aware of the information prior to the lodging of the Cleansing Notice on MAP, please explain why the information was not set out in the Cleansing Notice pursuant to the Act?
 9. Please confirm that CU6 is in compliance with the Listing Rules and, in particular, Listing Rule 3.1.
 10. Please confirm that CU6'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 CU6 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 **9:00 AM AEDT on Friday, 14 February 2025**.

You should note that if the information 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, CU6's obligation is to disclose the information 'immediately'. This may require the information to be disclosed before the deadline set out above and may require CU6 to request a trading halt immediately if trading in CU6's securities is not already halted or suspended.

Your response should be sent by e-mail to **ListingsComplianceSydney@asx.com.au**. It should not be sent directly to the ASX Market Announcements Office. This is to allow us to review your response to confirm that it is in a form appropriate for release to the market, before it is published on MAP.

Suspension

If you are unable to respond to this letter by the time specified above, ASX will likely suspend trading in CU6's securities under Listing Rule 17.3.

Listing Rules 3.1 and 3.1A

In responding to this letter, you should have regard to CU6'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 CU6'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 all or any part of this letter, your reply and any other related correspondence between us to the market under Listing Rule 18.7A. The usual course is for the correspondence to be released to the market.

Regards

ASX Compliance