

10 June 2025

ASX Compliance

By email: [listingscompliancesydney@asx.com.au](mailto:listingscompliancesydney@asx.com.au)

Dear Sir or Madam

**Response to Cleansing Notice Timing Query**

We refer to your correspondence dated 6 June 2025 (**Correspondence**) to Invion Limited (**Invion** or **IVX**) regarding the timing of the cleansing notice released by Invion to the ASX on 27 May 2025.

Capitalised terms not otherwise defined in this correspondence have the meaning ascribed to that term in the Correspondence.

Invion responds to each of the queries as raised in the Correspondence as follows:

**1. Does IVX consider the information disclosed in the Announcement and in particular,**

- ***"No adverse events identified by the Safety Review Committee (SRC) following the treatment of the first six patients in Invion's Phase I/II non-melanoma skin cancer (NMSC) trial."***
- ***"All data suggests that the treatment was well tolerated and feedback from clinicians indicated there were no signs of pain associated with the treatment, which is a significant benefit over other Photodynamic Therapy (PDT) treatments for NMSC."***
- ***"... observable reduction in the NMSC lesion size after a single treatment cycle at 15- and 30- days post treatment, while on average, untreated patient-matched lesions increased slightly in diameter over the same corresponding periods post treatment."***

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:

- the assets and liabilities, financial position and performance, profits and losses and prospects of IVX; or
- the rights and liabilities attaching to the relevant securities?

Yes.

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

Not applicable.

**3. Does IVX 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?**

Yes.

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

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Not applicable.

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

*Invion considers that the information to which question 3 relates is the information on efficacy, specifically that there is an “... observable reduction in the NMSC lesion size after a single treatment cycle at 15- and 30- days post treatment, while on average, untreated patient-matched lesions increased slightly in diameter over the same corresponding periods post treatment.”*

**6. If the answer to either limb in question 1 is “yes”, when did IVX first become aware of the relevant information in the Announcement? In answering this question, please specify the date and time when IVX first became aware of the relevant information, and in particular,**

- ***No adverse events identified by the Safety Review Committee (SRC) following the treatment of the first six patients in Invion’s Phase I/II non-melanoma skin cancer (NMSC) trial.”***
- ***“All data suggests that the treatment was well tolerated and feedback from clinicians indicated there were no signs of pain associated with the treatment, which is a significant benefit over other Photodynamic Therapy (PDT) treatments for NMSC.”***
- ***“... observable reduction in the NMSC lesion size after a single treatment cycle at 15- and 30- days post treatment, while on average, untreated patient-matched lesions increased slightly in diameter over the same corresponding periods post treatment.”***

**or any part thereof.**

On 25 May 2025, Invion received from a third-party consultant the information that early indications show an observable reduction in NMSC lesion size after a single treatment cycle (**Efficacy Data**). While Invion considered that the Efficacy Data was potentially significant, it was necessary for Invion to have the analysis further reviewed by its medical consultant, medical monitor and CRO staff to ensure that it was in fact material, to verify accuracy and confirm appropriateness for release to market. It was not until after market close on 28 May 2025 that these matters were confirmed. A final ASX announcement was urgently approved by the Board and was released promptly and without delay before market open on 29 May 2025.

On 26 May 2025, Invion received the minutes of the SRC confirming that there were no adverse events identified by the Safety Review Committee in Part 1 of the adaptive trial and proceeding to Part 2 of the trial. The clinician feedback regarding no signs of pain associated with the treatment was received over a period of time. Given that the trial has not been completed (and these are not end points), Invion does not consider that, on a standalone basis, the information would be information for which it is reasonable for investors and their professional advisers to expect to find in a disclosure document. However, this information was included in the Announcement to provide full disclosure to the market.

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

Yes.

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**8. If IVX 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?**

As set out in Invion's ASX announcement dated 10 June 2025 (**Further Announcement**), Invion notes the following:

- At the time the Cleansing Notice was lodged, Invion did not consider that there was 'excluded information' as set out in sections 708A(7) and 708A(8) of the Corporations Act that was required to be included in the Notice pursuant to section 708A(6)(e) of the Corporations Act. Invion formed this view on the basis that the information had not yet been verified by its medical consultant, medical monitor and CRO staff.
- Invion has subsequently been advised that at the time the Notice was lodged, Invion was likely in possession of information to which Listing Rule 3.1A would have excluded from disclosure under Listing Rule 3.1 and within the definition of 'excluded information.'
- Out of an abundance of caution, Invion made the Further Announcement pursuant to and in accordance with section 708A(9)(c) of the Corporations Act for the purposes of correcting the Notice, which may be considered to be defective.

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

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

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

Invion confirms that the responses to the questions above have been authorised and approved by the Board of Invion.

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**Sign up at Invion's Investor Hub to receive regular updates, provide feedback and participate in discussions:** <https://investors.inviongroup.com/>

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## **ASX ANNOUNCEMENT**

### **About Invion**

Invion is a life-science company that is leading the global research and development of the Photosoft™ technology for the treatment of a range of cancers, atherosclerosis and infectious diseases. Invion holds the exclusive Australia and New Zealand license rights and exclusive distribution rights to Hong Kong and the rest of Asia Pacific, excluding China, Macau, Taiwan and Japan, to the Photosoft technology for all cancer indications. It also holds the exclusive rights to the technology in Asia and Oceania, excluding China, Hong Kong, Taiwan, Macau, the Middle East and Russia for atherosclerosis and infectious diseases, and subsequently acquired the rights to the United States, Canada and Hong Kong for infectious diseases. Research and clinical cancer trials are funded by the technology licensor, RMW Cho Group Limited. Invion is listed on the ASX (ASX: IVX).

### **About Photodynamic Therapy (PDT)**

Invion is developing Photosoft™ technology as a novel next generation Photodynamic Therapy (PDT). PDT uses non-toxic photosensitisers and light to selectively kill cancer cells and promote an anti-cancer immune response. Less invasive than surgery and with minimal side effects, PDT offers an alternative treatment option aimed at achieving complete tumour regression and long-lasting remission. PDT has also demonstrated broad-spectrum activity across multiple infectious diseases, including bacteria, fungi and viruses. Photosoft has the potential to address the global challenge of antibiotic-resistant "superbugs".



6 June 2025

Reference: 109830

Ms Melanie Leydin  
Company Secretary  
Invion Limited  
Level 4 100 Albert Road  
SOUTH MELBOURNE VIC 3205

By email

Dear Ms Leydin

**Invion Limited ('IVX'): Cleansing Notice Timing**

ASX refers to the following:

- A. IVX's announcement titled 'Section 708A Cleansing Statement' released on the ASX Market Announcements Platform ('MAP') at 1:57 PM AEST on 27 May 2025 (the 'Cleansing Notice'), disclosing amongst other things:

"...

*(d) as at the date of this notice the Company, as a disclosing entity under the Corporations Act, has complied with:*

*(i) the provisions of Chapter 2M of the Corporations Act as they apply to the Company and;*

*(ii) section 674 of the Corporations Act as it applies to the Company; and*

*(e) as at the date of this announcement, other than as set out below there is no excluded information of the type referred to in Sections 708A(7) and 708A(8) of the Corporations Act.*

*Invion is currently in discussions with RMW Cho Group Limited to expand Invion's rights to the Photosoft™ technology to other territories and/or indications. These discussions are incomplete and preliminary in nature and there is no certainty that a binding agreement will be reached. RMW Cho Group Limited is the licensor of the Photosoft™ technology."*

- B. IVX's announcement titled 'Encouraging SRC Findings on Ph I/II Skin Cancer Trial' (the 'Announcement') released on MAP at 8:53 AM AEST on 29 May 2025, disclosing the following:

- "No adverse events identified by the Safety Review Committee (SRC) following the treatment of the first six patients in Invion's Phase I/II non-melanoma skin cancer (NMSC) trial."*
- "All data suggests that the treatment was well tolerated and feedback from clinicians indicated there were no signs of pain associated with the treatment, which is a significant benefit over other Photodynamic Therapy (PDT) treatments for NMSC."*
- "... observable reduction in the NMSC lesion size after a single treatment cycle at 15- and 30- days post treatment, while on average, untreated patient-matched lesions increased slightly in diameter over the same corresponding periods post treatment."*

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

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

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- (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 IVX to respond separately to each of the following questions.

1. Does IVX consider the information disclosed in the Announcement and in particular,

- "No adverse events identified by the Safety Review Committee (SRC) following the treatment of the first six patients in Invion's Phase I/II non-melanoma skin cancer (NMSC) trial."*
- "All data suggests that the treatment was well tolerated and feedback from clinicians indicated there were no signs of pain associated with the treatment, which is a significant benefit over other Photodynamic Therapy (PDT) treatments for NMSC."*

- *“... observable reduction in the NMSC lesion size after a single treatment cycle at 15- and 30- days post treatment, while on average, untreated patient-matched lesions increased slightly in diameter over the same corresponding periods post treatment.”*

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:

- the assets and liabilities, financial position and performance, profits and losses and prospects of IVX; or
  - 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 IVX 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”, when did IVX first become aware of the relevant information in the Announcement? In answering this question, please specify the date and time when IVX first became aware of the relevant information, and in particular,
    - *“No adverse events identified by the Safety Review Committee (SRC) following the treatment of the first six patients in Invion’s Phase I/II non-melanoma skin cancer (NMSC) trial.”*
    - *“All data suggests that the treatment was well tolerated and feedback from clinicians indicated there were no signs of pain associated with the treatment, which is a significant benefit over other Photodynamic Therapy (PDT) treatments for NMSC.”*
    - *“... observable reduction in the NMSC lesion size after a single treatment cycle at 15- and 30- days post treatment, while on average, untreated patient-matched lesions increased slightly in diameter over the same corresponding periods post treatment.”*

or any part thereof.

7. If IVX first became aware of the relevant information before lodging the Cleansing Notice on MAP, was IVX relying on the provisions of Listing Rule 3.1A not to release the information before IVX lodged the Announcement on MAP?
8. If IVX 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 IVX is in compliance with the Listing Rules and, in particular, Listing Rule 3.1.
10. Please confirm that IVX’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 IVX 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 AEST on Wednesday, 11 June 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, IVX’s obligation is to disclose the information ‘immediately’. This may require the information to be disclosed before the deadline set

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out above and may require IVX to request a trading halt immediately if trading in IVX'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 IVX's securities under Listing Rule 17.3.

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

In responding to this letter, you should have regard to IVX'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 IVX'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

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ASX Compliance