

27 August 2025

ASX Compliance

By email: listingscompliancesydney@asx.com.au

Dear Sir or Madam

**Response to ASX Aware Letter**

We refer to your correspondence dated 22 August 2025 (**Correspondence**) to Invion Limited (**Invion** or **IVX**) regarding the ASX Announcement made by IVX on 20 August 2025 titled: "Orphan Drug Designation Granted by U.S. FDA For Anal Cancer".

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, or any part thereof, to be information that a reasonable person would expect to have a material effect on the price or value of its securities?**

Yes.

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

Not applicable.

3. **When did IVX first become aware of the Information referred to in question 1 above?**

In the late afternoon of 19 August 2025.

4. **If IVX first became aware of the Information referred to in question 1 before the date of the Announcement, did IVX make any announcement prior to that date which disclosed the Information? If not, please explain why the Information was not released to the market at an earlier time, commenting specifically on:**

**4.1 when you believe IVX was obliged to release the Information under Listing Rules 3.1 and 3.1A; and**

**4.2 what steps IVX took to ensure that the Information was released promptly and without delay.**

Invion did not make a prior announcement regarding the subject matter of the "Orphan Drug Designation Granted by U.S. FDA For Anal Cancer" announcement, dated 20 August 2025.

An earlier announcement regarding the orphan drug designation (**information**) had not been made as an officer of the company only became aware of the information around the time a trading pause was put in place by ASX in the afternoon of 19 August 2025. Upon investigation Invion uncovered that there had been online speculation regarding the FDA's decision to grant orphan drug designation. At this time Invion took immediate steps to verify this information and to contact its US-based consultant to confirm the details of the FDA decision. IVX also immediately contacted the ASX to discuss a trading halt.

## ASX ANNOUNCEMENT

The FDA decision was not communicated to Invion prior to becoming available on the FDA website. Invion has kept in regular communication with its US-based consultant regarding the FDA process, including sending a status update request by email to the consultant on the morning of 19 August 2025 (AEST), but had not received any notification from the consultant.

**5. 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.

**6. 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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**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).

## **ASX ANNOUNCEMENT**

### **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".



22 August 2025

Reference: 111891

Ms Melanie Leydin  
Company Secretary  
Invion Limited  
Suite 2 Level 11 385 Bourke Street  
MELBOURNE VIC 3000

By email

Dear Ms Leydin

**Invion Limited ('IVX'): ASX Aware Letter**

ASX refers to the following:

- A. IVX's announcement titled "Orphan Drug Designation Granted by U.S. FDA For Anal Cancer" (the 'Announcement') released on the ASX Market Announcements Platform at 9:50 AM on 20 August 2025 disclosing that the US Food and Drug Administration has granted Orphan Drug Designation in respect to INV043 for the treatment of anal cancer (the 'Information').
- B. 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.
- C. 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."*
- D. Section 4.4 in *Guidance Note 8: Continuous Disclosure: Listing Rules 3.1 – 3.1B* titled "When does an entity become aware of information?"
- E. Listing Rule 3.1A, which sets out exceptions from the requirement to make immediate disclosure as follows.

*"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."*

- F. The concept of “confidentiality” detailed in section 5.8 of Guidance Note 8 *Continuous Disclosure: Listing Rules 3.1 – 3.1B*. In particular, the Guidance Note states that:

*“Whether information has the quality of being confidential is a question of fact, not one of the intention or desire of the entity. Accordingly, even though an entity may consider information to be confidential and its disclosure to be a breach of confidence, if it is in fact disclosed by those who know it, then it is no longer a secret and it ceases to be confidential information for the purposes of this rule.”*

### **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, or any part thereof, to be information that a reasonable person would expect to have a material effect on the price or value of its securities?
2. If the answer to any part of question 1 is “no”, please advise the basis for that view.
3. When did IVX first become aware of the Information referred to in question 1 above?
4. If IVX first became aware of the Information referred to in question 1 before the date of the Announcement, did IVX make any announcement prior to that date which disclosed the Information? If not, please explain why the Information was not released to the market at an earlier time, commenting specifically on:
  - 4.1 when you believe IVX was obliged to release the Information under Listing Rules 3.1 and 3.1A; and
  - 4.2 what steps IVX took to ensure that the Information was released promptly and without delay.
5. Please confirm that IVX is in compliance with the Listing Rules and, in particular, Listing Rule 3.1.
6. 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, 27 August 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 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 the ASX Market Announcements Platform.

### **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**

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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