

4 August 2022

Australian Securities Exchange Limited  
40 Central Park  
152 – 158 St Georges Terrace  
PERTH WA 6000  
Attention: Barbara Lim  
By email only: barbara.lim@asx.com.au

Dear Madam,

### **ASX FURTHER AWARE QUERY**

We refer to the aware query issued by the Australian Securities Exchange on Tuesday, 2 August 2022 and comment as follows:

- 1. Please provide a copy of the email received by ZLD at approximately 8.00pm (WST) on 11 July 2022 by which ZLD states it first became aware it had received formal regulatory approval in Germany ('Email') (not for release to the market).**

Provided.

- 2. ZLD states that it became aware that it had received formal regulatory approval by way of the Email, however it also states that that the Email was 'informal' and contained information regarded as matters of supposition. Please clarify why ZLD characterised the information in the Email in this way, with reference to the ASX guidance set out in paragraph H.**

Zelira characterised the information is informal as:

- The Email took the form of an informal conversation between the sender and Mr Greg Blake of Zelira.
- The Email was not clear on what was meant by federal authority, local authority and what steps remained in order to be in a position to announce.
- It was the Company's view that it was important it understood the distinction its partner was making before it announced the Federal approval. As such, until this issue was satisfactorily clarified, there was uncertainty and the company was not in a position to announce.

- 3. Please confirm the time and date that ZLD received approval from its German commercialisation partner for the Announcement and how ZLD received the approval.**

Following ZLD being placed in a trading halt, ZLD re-sought feedback and approval for both the context and the content of the announcement. At approximately 6 AM, Wednesday, 13 July 2022, Zelira received an email from its commercial partner, that did not raise any concerns regarding the content of the announcement but noted its commercial partner may have comments on the wording. Following receipt of this email, Zelira was satisfied that the information within the announcement was sufficiently definite to warrant disclosure.

**4. Please confirm that ZLD is complying with the Listing Rules and, in particular, Listing Rule 3.1.**

The Company confirms that in its opinion it is, and has been at all times, in compliance with Listing Rule 3.1.

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

The Company confirms its responses above have been authorised and approved in accordance with its published continuous disclosure policy or otherwise by its board or an officer of the Company with delegated authority from the board to respond to ASX on disclosure matters.

Yours sincerely

A handwritten signature in black ink, appearing to be 'Tim Slate', written over a faint, circular, scribbled background.

Tim Slate  
**Company Secretary**

**For further information please contact:**

**Company**

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**About Zelira Therapeutics ([www.zeliratx.com](http://www.zeliratx.com))**

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Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF) Zelira is a leading global biopharmaceutical company developing, manufacturing and marketing clinically validated cannabinoid-based medicines. Zelira owns a portfolio of proprietary revenue generating products and a pipeline of candidates undergoing clinical development positioned to enter global markets. The Company is focused on developing and clinically validating branded cannabinoid-based medicines in its prescription [Rx] business for the treatment of a variety of medical conditions including insomnia, autism and chronic non-cancer pain as well as offering over the counter [OTC] products.

Zelira Rx business generates revenue from two proprietary medications, HOPE™ and Zenivol®. The Company has two proprietary formulations under the HOPE™ brand that are generating revenue in Australia, Washington, D.C., Pennsylvania and Louisiana.

Zelira is also generating revenue in Australia from its proprietary and patented Zenivol® – the world's first clinically validated cannabinoid drug for treatment of chronic insomnia. Zelira will also be expanding commercialisation of Zenivol® into New Zealand and Germany via its German commercialisation partner Adjupharm GmbH following recent approval from German regulatory authority BfArM.

Zelira's OTC products in the oral and dermatology health care sectors are also generating revenue. Zelira, in partnership with SprinJeneCBD, launched a full line of oral care products, currently generating revenue in the US. The SprinJeneCBD toothpaste product is the first of several scientifically formulated, hemp-derived, oral care products containing cannabinoids, blackseed oil and zinc utilising proprietary and patented technology. Zelira also launched in 2021 the RAF FIVE™ brand, which consists of five OTC acne treatment products using a proprietary formulation incorporating Cannabidiol (CBD).

Zelira has developed Enhanced Distillate Capture and Dissolution Matrix (EDCDM) technology that solves the problem of non-uniformity and separation of cannabinoid form power bed, opening new ways to develop pharmaceutical grade solid oral dosage forms such as capsules and tablets. Zelira will be assessing opportunities for commercialisation of this technology.

The Company has conducted its work in partnership with world-leading researchers and organisations which since inception includes Curtin University in Perth, Australia; the Telethon Kids Institute in Perth, Australia; the University of Western Australia, in Perth, Australia; St Vincent's Hospital in Melbourne, Australia; and the Children's Hospital of Philadelphia (CHOP) in the United States.



2 August 2022

Reference: 56070

Mr Tim Slate  
Company Secretary  
Zelira Therapeutics Limited

By email

Dear Mr Slate

**Zelira Therapeutics Limited ('ZLD'): General – Further Aware Query**

ASX refers to the following:

A. ASX's price query letter dated 12 July 2022 ('Price Query') and ZLD's response to the Price Query dated 13 July 2022, released together on the ASX Market Announcements Platform ('MAP') at 7:33 AM AWST on 13 July 2022 in which ZLD relevantly responded as follows (response in italics):

1. Is ZLD aware of any information concerning it that has not been announced to the market which, if known by some in the market, could explain the recent trading in its securities?

*Yes, the Company is very recently in possession of German regulatory authority BfArM results with respect to its clinically validated cannabinoid-based insomnia medication, Zenivol.*

2. If the answer to question 1 is "yes".

- a. Is ZLD relying on Listing Rule 3.1A not to announce that information under Listing Rule 3.1? Please note that the recent trading in ZLD's securities would suggest to ASX that such information may have ceased to be confidential and therefore ZLD may no longer be able to rely on Listing Rule 3.1A. Accordingly, if the answer to this question is "yes", you need to contact us immediately to discuss the situation.

*The Company was in the process of preparing an announcement in relation to this matter, and was relying on Listing Rule 3.1A.2 not to announce that information under Listing Rule 3.1 on the basis that a very limited number of employees withing (sic) the Company were in possession of the information and the Company considered the information to be confidential*

*Upon the ASX forming the view that the information ceased to be confidential a trading halt was requested.*

*Notwithstanding the concurrent timing, the Board's view is that the recent increase in share price was most likely driven by an increase in small volume buyers being met by a reduction in small volume sellers that (sic) those seen over recent weeks. The Company considered that the movement in share price indicated that investors had begun to identify the unique investment opportunity Zelira's multiple shots on goal strategy presents as opposed to directly being a response to the news referred to in question 1 above.*

- b. Can an announcement be made immediately? Please note, if the answer to this question is "no", you need to contact us immediately to discuss requesting a trading halt (see below).

*Yes, following receipt of approval from its commercialization partner with respect to some content within the announcement, the Company intends to make an announcement prior to commencement of trading on 13 July 2022.*

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- B. ZLD's announcement titled 'Zenivol® achieves major milestone with formal regulatory approval received in Germany' released on MAP at 7:33 AM AWST on 13 July 2022 ('Announcement'). The Announcement states, amongst other matters, that its cannabinoid-based insomnia medication, Zenivol®, has received formal approval from the German regulatory authority BfArM (The Federal Institute for Drugs and Medical Devices Bundesinstitut für Arzneimittel und Medizinprodukte) via its German commercialisation partner Adjupharm GmbH ('Information').
- C. ASX's aware query letter dated 14 July 2022 ('Aware Query') and ZLD's response to the Aware Query released together on MAP at 3:39 PM AWST on 18 July 2022 in which ZLD responded as follows (response in italics):

1. Does ZLD consider the Information 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 question 1 is "no", please advise the basis for that view.

*N/A*

3. When did ZLD first become aware of the Information?

*The Company first became aware it had received formal regulatory approval received in Germany at approximately 8.00pm (WST) 11 July 2022.*

4. If the answer to question 1 is "yes" and ZLD first became aware of the Information before 13 July 2022 (being the date of the Announcement), did ZLD make any announcement prior to 13 July 2022 which disclosed the Information? If so, please provide details. If not, please explain why this Information was not released to the market at an earlier time, commenting specifically on when you believe ZLD was obliged to release the Information under Listing Rules 3.1 and 3.1A and what steps ZLD took to ensure that the Information was released promptly and without delay.

*The Company was satisfied it was in compliance with Listing Rule 3.1 and 3.1A as:*

- The Company became aware of the information my (sic) way of an informal email whereby the Company commenced preparing an ASX announcement in an appropriate form for release. Given the form by which the information was received, the Company sought to ensure that it's understanding of the information was accurate and certain as to ensure the Company did not incorrectly announce the receipt of regulatory approval. The Company considered that, until approval was received, the information comprised matters of supposition and until this was resolved, a reasonable person would not expect the information to be disclosed. Due to time zone restrictions, the Company was unable to obtain approval from its commercialisation partner on 12 July 2022.*
- Throughout the day on 12 July 2022, the Company took steps to ensure that the information remained confidential and sought and received confirmation from its employees that the information remained confidential.*
- The share price increased from \$1.02 to \$1.54 between 6 July 2022 and 11 July 2022, prior to the Company receiving formal approval.*
- The trades during 12 July 2022 were sporadic, relatively small in value and consistent with trading prior to the Company becoming aware of the approval.*

*However, Zelira considered it was obliged to cease the trading of its securities upon the ASX forming the view that the information ceased to be confidential. Therefore, a trading halt was requested until the announcement was able to be released.*

5. Please confirm that ZLD is complying with the Listing Rules and, in particular, Listing Rule 3.1.

*The Company confirms that in its opinion it is, and has been at all times, in compliance with Listing Rule 3.1.*

6. Please confirm that ZLD'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 ZLD with delegated authority from the board to respond to ASX on disclosure matters.

*The Company confirms its responses above have been authorised and approved in accordance with its published continuous disclosure policy or otherwise by its board or an officer of the Company with delegated authority from the board to respond to ASX on disclosure matters.*

- 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. 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 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."*

- G. ASX's policy position on the concept of "confidentiality", which is 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 listed 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 ceases to be confidential information for the purposes of this rule."*

- H. Section 5.5 of Guidance Note 8, which sets out ASX's policy position on matters of supposition or that are insufficiently definite to warrant disclosure, including the following:

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*“This category of information is excluded from disclosure because of its propensity to misinform or mislead the market. The term “supposition” refers to something which is assumed or believed without knowledge or proof. Information about a matter will be “insufficiently definite to warrant disclosure” if:*

- the information is so vague, embryonic or imprecise;*
- the veracity of the information is so open to doubt; or*
- the likelihood of the matter occurring, or its impact if it does occur, is so uncertain,*

*that a reasonable person would not expect it to be disclosed to the market. In some cases, information in this category may be so uncertain or indefinite that it is not in fact market sensitive and therefore not required to be disclosed under Listing Rule 3.1, regardless of whether it falls within the carve-outs from disclosure in Listing Rule 3.1A.”*

### **Request for information**

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

1. Please provide a copy of the email received by ZLD at approximately 8.00pm (WST) on 11 July 2022 by which ZLD states it first became aware it had received formal regulatory approval in Germany ('Email') (not for release to the market).
2. ZLD states that it became aware that it had received formal regulatory approval by way of the Email, however it also states that the Email was 'informal' and contained information regarded as matters of supposition. Please clarify why ZLD characterised the information in the Email in this way, with reference to the ASX guidance set out in paragraph H.
3. Please confirm the time and date that ZLD received approval from its German commercialisation partner for the Announcement and how ZLD received the approval.
4. Please confirm that ZLD is complying with the Listing Rules and, in particular, Listing Rule 3.1.
5. Please confirm that ZLD'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 ZLD 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 **11:45 AM AWST Friday, 5 August 2022**. 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, ZLD'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 ZLD to request a trading halt immediately.

Your response should be sent to me by e-mail at **ListingsCompliancePerth@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.

### **Suspension**

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

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

In responding to this letter, you should have regard to ZLD'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 ZLD'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.

Yours sincerely

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**Barbara Lim**

Adviser, Listings Compliance (Perth)