ACN 103 782 378

5 December 2017

ASX Limited
40 Central Park
152 – 158 St Georges Terrace
PERTH WA 6000

Attention: Isabelle Andrews
By email only: isabelle.andrews@asx.com.au

Dear Ms Andrews,

Zelda Therapeutics Limited ("ZLD"): Aware Letter

We refer to your letter dated 30 November 2017, and provide clarification and response to your questions as follows:

Background on Approval Processes

By way of initial background, ZLD advises that for Schedule 8 drugs, such as medicinal cannabis, there are various levels of approvals required before a clinical trial is able to commence. Clinical trials cannot commence until all these approvals have been received, which are as follows:

1) *Human Research Ethics Committee (HREC) – to approve the protocol for the clinical trial;*
2) *Therapeutic Goods Administration (TGA) through Clinical Trial Notification – approving the GMP product (drug) with certificates of analysis and declaration of conformity of the drug; and*
3) *State level approvals which for ZLD's study is WA Department of Health – to approve the prescribing of the drug for the trial.*

Through this multi-layer process once any change is made to the clinical trial protocol along the approval process, i.e. by TGA or WA Department of Health, the applicant is required to go back to make changes and amendments which need to be re-approved by HREC before the trial can commence.

ZLD is of the view that given, if any change is required any stage, the Company is required to recommence the approval process, it is inappropriate to make any announcement in relation to the receipt of approvals until all approvals, enabling the clinical trial to commence, have been received because:

1) *It may result in ZLD making multiple announcements relating to the approvals for the same clinical trial application; and*
2) *ZLD is not in a position to commence a clinical trial without all these approvals.*

ZLD considers it paramount it adheres to the strict regulatory environment surrounding medicinal cannabis whilst State and Federal policies are formalised and established. ZLD considers any announcements made prior to final approval may be deemed misleading by State and Federal

regulators, and if so, may have a direct impact on ZLD's capacity to conduct research within Australia and subsequently have a negative impact on its current clinical trial programmes focused on autism, insomnia and eczema as well as its pre-clinical trial research programme examining the effect of cannabinoids in breast, brain and pancreatic cancers.

Response to ASX Queries

In Relation to the Human Research Ethics Committee Approval

Given the background above, and utilising the numbering in your letter, ZLD responds as follows:

1. When did ZLD first apply for the approval from the Human Research Ethics Committee?

   ZLD initially applied for the approval on 26 April 2017.

2. Does ZLD consider the information or any part thereof contained in the Announcement, namely the approval granted by the Human Research Ethics Committee for the Clinical Trial to be information that a reasonable person would expect to have a material effect on the price or value of its securities?

   Yes.

3. If the answer to question 2 is "no", please advise the basis for that view.

   Not applicable.

4. When did ZLD first become aware of the approval granted by the Human Research Ethics Committee for the Clinical Trial? In answering this question, please state the date and time that ZLD first became aware of the information (or any part thereof) in the Announcement.

   Initial approval for the protocol for the clinical trial from Bellberry HREC was on 22 June 2017. However, as outlined above, this does not allow you to commence the trial until you have TGA and WA Department of Health approvals (see below for these dates), and final approval was given by Bellberry after multiple amendments were made to the protocol based on changes required by the TGA and WA Department of Health through their approval process.

   This final approval by Bellberry HREC was granted on 28 November 2017.

5. If ZLD first became aware of the approval granted by the Human Research Ethics Committee before 29 November 2017, did ZLD make any announcement prior to the relevant date 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.

   ZLD first became aware of the HREC approval to be able to commence the trial around 8am, 28 November 2017. Upon becoming aware of the approval, ZLD immediately undertook the steps necessary for the drafting and approval of the announcement that was subsequently released to ASX.

   ZLD notes there was an unforeseen delay regarding the final step in its approval process, being final approval from the executive director. ZLD notes the executive director was travelling internationally and had been regularly responding to correspondence regarding the drafting

of the ASX announcement however was unable to provide final approval. ZLD expected to receive approval to release the announcement without delay and as such elected not to go in to a trading halt. The final approval was received after market close on 28 November 2017, with the announcement being made promptly following the satisfaction of this requirement.

In Relation to the Therapeutics Goods Administration ("TGA") approval

6. When did ZLD first apply for the approval from the TGA? In answering this question, please state the date that ZLD applied for the approval.

   Clinical Trial Notification (CTN) was applied for by the TGA on 1 September 2017.

7. Does ZLD consider the information or any part thereof contained in the Announcement, namely the approval granted by the TGA for the Clinical Trial to be information that a reasonable person would expect to have a material effect on the price or value of its securities?

   Yes.

8. If the answer to question 7 is "no", please advise the basis for that view.

   Not applicable.

9. When did ZLD first become aware of the approval granted by the TGA for the Clinical Trial? In answering this question, please state the date and time that ZLD first became aware of the information (or any part thereof) in the Announcement.

   The TGA CTN approval was granted on 3 October 2017. After this approval ZLD was required to seek approval from WA Department of Health for authorisation to prescribe the drug for the trial. The trial cannot commence without this state approval.

10. If ZLD first became aware of the approval granted by TGA before 29 November 2017, did ZLD make any announcement prior to the relevant date 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.

    As outlined above, ZLD did not release any announcement relating to the receipt of this approval as it did not of itself allow any clinical trial to commence.

In Relation to the Western Australian Department of Health approval

11. When did ZLD first apply for the approval from the Western Australian Department of Health? In answering this question, please state the date that ZLD applied for the approval.

    Approval was sought from the WA Department of Health on 11 October 2017.

12. Does ZLD consider the information or any part thereof contained in the Announcement, namely the approval granted by the Western Australian Department of Health for the Clinical Trial to be information that a reasonable person would expect to have a material effect on the price or value of its securities?

    Yes.

13. If the answer to question 12 is "no", please advise the basis for that view.

Not applicable.

14. When did ZLD first become aware of the approval granted by the Western Australian Department of Health for the Clinical Trial? In answering this question, please state the date and time that ZLD first became aware of the information (or any part thereof) in the Announcement.

    ZLD became aware of approval by WA Department of Health on 17 November 2017, subject to a number of amendments. As detailed above, ZLD was required to re-commence the approval process as a result of these amendments. ZLD received verbal indications from HREC that a response regarding the protocol application could take several weeks, whereby HREC would either approve the protocol or require additional amendments to be made, which may result in further delays.

    Final approval was granted by Bellberry HREC on 28 November 2017 to commence the clinical trial.

15. If ZLD first became aware of the approval granted by the Western Australian Department of Health before 29 November 2017, did ZLD make any announcement prior to the relevant date 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.

    As outlined above, ZLD did not release any announcement relating to the receipt of this approval as it did not of itself allow any clinical trial to commence.

16. Please confirm that the Company is in compliance with the listing rules and, in particular, listing rule 3.1.

    The Company is in compliance with the Listing Rules of the ASX and, in particular, Listing Rule 3.1.

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

    I confirm that the Company'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 the Company with delegated authority from the board to respond to ASX on disclosure matters.

Yours sincerely

Tim Slate
Company Secretary

About Zelda Therapeutics (www.zeldatherapeutics.com**)**

Zelda Therapeutics ("Zelda") is an Australian-based bio-pharmaceutical company that is focused on developing a range of cannabinoid-based formulations for the treatment of a variety of medical conditions. The Company has a two-pronged strategy comprising:

- A human clinical trial programme focused on insomnia, autism and eczema with activities in Australia and Chile.
- A pre-clinical research programme examining the effect of cannabinoids in breast, brain and pancreatic cancer. It has partnered with the world's leading cancer cannabis researchers at Complutense University Madrid in Spain to conduct certain pre-clinical work testing cannabis-based formulations known to have an effect in humans in order to generate data packs in a form expected by regulators and the pharmaceutical industry. A similar programme is in place with the Australian Telethon Kids Institute targeting paediatric brain cancer and Curtin University targeting pancreatic cancer.

30 November 2017

Mr Tim Slate
Company Secretary
Zelda Therapeutics Limited
Level 6 105 St Georges Terrace
Perth WA 6000

By email:

Dear Mr Slate

Zelda Therapeutics Limited ("ZLD"): AWARE LETTER

ASX Limited ("ASX") refers to the following:

A. The change in the price of ZLD's securites from a low of $0.09 to an intra-day high of $0.117 on 21 November 2017.

B. ZLD's response to the ASX price and volume query lodged on the ASX Market Announcements Platform and released at 10:16 am (AEDT) on 22 November 2017 (the "Announcement"), disclosing, amongst other things, that the Company was not aware of any information concerning it that had not been announced to the market, but that the Company was involved in ongoing discussions in relation to ethics approvals. However, that no formal agreements had been entered into.

C. ZLD's announcement entitled "Australian Regulators Approve Zelda Insomnia Clinical Trial" lodged on the ASX Market Announcements Platform and released at 08:20 am (AEDT) on 29 November 2017 (the "Announcement"), disclosing, amongst other things, that the Company had received full approval from the Human Research Ethics Committee, the Therapeutics Goods Administration ("TGA") and the Western Australian Department of Health in relation to the clinical trial of its medical cannabis formulation on chronic insomnia patients at the University of Western Australia ("Clinical Trial").

D. The change in the price of ZLD's securities following the release of the Announcement, from a closing price of $0.115 on Tuesday 28 November 2017 to an intra-day high of $0.155 on Wednesday, 29 November 2017.

E. Listing Rule 3.1, which requires a listed entity to give ASX immediately 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.

F. 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"*.

G. 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."*

H. 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."*

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

In Relation to the Human Research Ethics Committee Approval

1. When did ZLD first apply for the approval from the Human Research Ethics Committee? In answering this question, please state the date that ZLD applied for the approval.

2. Does ZLD consider the information or any part thereof contained in the Announcement, namely the approval granted by the Human Research Ethics Committee for the Clinical Trial to be information that a reasonable person would expect to have a material effect on the price or value of its securities?

3. If the answer to question 2 is "no", please advise the basis for that view.

4. When did ZLD first become aware of the approval granted by the Human Research Ethics Committee for the Clinical Trial? In answering this question, please state the date and time that ZLD first became aware of the information (or any part thereof) in the Announcement.

5. If ZLD first became aware of the approval granted by the Human Research Ethics Committee before 29 November 2017, did ZLD make any announcement prior to the relevant date 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.

In Relation to the Therapeutics Goods Administration ("TGA") approval

6. When did ZLD first apply for the approval from the TGA? In answering this question, please state the date that ZLD applied for the approval.

7. Does ZLD consider the information or any part thereof contained in the Announcement, namely the approval granted by the TGA for the Clinical Trial to be information that a reasonable person would expect to have a material effect on the price or value of its securities?

8. If the answer to question 7 is "no", please advise the basis for that view.

9. When did ZLD first become aware of the approval granted by the TGA for the Clinical Trial? In answering this question, please state the date and time that ZLD first became aware of the information (or any part thereof) in the Announcement.

10. If ZLD first became aware of the approval granted by TGA before 29 November 2017, did ZLD make any announcement prior to the relevant date 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.

In Relation to the Western Australian Department of Health approval

11. When did ZLD first apply for the approval from the Western Australian Department of Health? In answering this question, please state the date that ZLD applied for the approval.

12. Does ZLD consider the information or any part thereof contained in the Announcement, namely the approval granted by the Western Australian Department of Health for the Clinical Trial to be information that a reasonable person would expect to have a material effect on the price or value of its securities?

13. If the answer to question 12 is "no", please advise the basis for that view.

14. When did ZLD first become aware of the approval granted by the Western Australian Department of Health for the Clinical Trial? In answering this question, please state the date and time that ZLD first became aware of the information (or any part thereof) in the Announcement.

15. If ZLD first became aware of the approval granted by the Western Australian Department of Health before 29 November 2017, did ZLD make any announcement prior to the relevant date 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.

When and where to send your response

This request is made under, and in accordance with, Listing Rule 18.7. Your response is required as soon as reasonably possible and, in any event, by not later than half an hour before the start of trading **(i.e 6:30 a.m. WST) on Wednesday 6 November**. If we do not have your response by then, ASX will have no choice but to consider suspending trading in ZLD's securities under Listing Rule 17.3.

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.

ASX reserves the right to release a copy of this letter and your response on the ASX Market Announcements Platform under Listing Rule 18.7A. Accordingly, your response should be in a form suitable for release to the market.

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

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.

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 ZLD'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 may 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*.

If you have any queries or concerns about any of the above, please contact me immediately.

Yours sincerely

[Sent electronically without signature]

Isabelle Andrews
Adviser Listing Compliance (Perth)