

Kate Kidson Senior Advisor, Listings Compliance, Melbourne ASX Compliance

5 February 2014

Dear Kate,

With reference to your Price Query letter of 4th February 2014, I provide the following information (using your numbering):

1. The Company is not aware of any information concerning it that has not been announced which, if known, could be an explanation for recent trading in the securities of the Company.

# 2. Not applicable

On January 31, 2014, the U.S. Food and Drug Administration (FDA) issued a Drug Safety Communication (DSC), which stated the FDA is investigating the risk of stroke, heart attack (myocardial infarction) and death in men taking FDA-approved testosterone products. These Drug Safety Communications (DSCs) are not uncommon. The FDA has not concluded that FDA-approved testosterone treatments increase the risk of stroke, heart attack, or death. The FDA stated it will continue to evaluate and communicate its final conclusions and recommendations once its evaluation is completed. Historically, this process has taken many months to complete. FDA stated that patients should not stop taking prescribed testosterone products without first discussing any questions or concerns with their health care professionals.

The DSC indicates that the FDA has been monitoring this risk and a reassessment was prompted by two recent publications: "Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels," published on November 5, 2013, in the Journal of the American Medical Association and "Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men," published in the January 29 online edition of the journal PLOS ONE. These studies have generated significant media interest and coverage in the last 24 hours.

Lilly regularly reviews available safety information, including cardiovascular safety information, to determine if updates to the label are needed, and routinely works with regulatory agencies to further understand and communicate the risks and benefits of testosterone replacement therapy. Lilly provides several warnings and precautions related to cardiovascular risk in product labels for Axiron. These include warnings and precautions on risks of thickening of the blood and associated blood clots; swelling with heart failure in patients with pre-existing heart disease; and changes in blood cholesterol. The U.S. medication guide instructs patients to tell their health care provider before using Axiron if they have heart problems. The U.S. label notes the absence of long-term safety data to assess a potential increase in cardiovascular risk in patients over 65 years of age taking Axiron.



Lilly and Acrux are reviewing the articles which triggered the DSC and continue to evaluate the studies. A report was publicised, and circulated on the 4th February 2014, which misrepresented the articles conclusions and the FDA DSC, and Acrux believes that this triggered the recent trading in its securities.

Axiron is a prescription medication, approved by the FDA, for men with certain conditions associated with a deficiency or absence of testosterone. Lilly does not condone the use of the medicine for off-label purposes and encourages men to talk with their physician to weigh the benefits and risks before taking any prescription medication.

3. The Company is in compliance with the listing rules and, in particular, listing rule 3.1.

Yours sincerely,

Tony DiPietro

CFO & Company Secretary



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4 February 2014

Mr Tony Di Pietro Company Secretary Acrux Limited

Dear Tony,

## Acrux Limited (the "Entity"): ASX price query

We have noted a change in the price of the Entity's securities from a close yesterday of \$2.32 to an intraday low of \$2.09 at the time of writing today. We have also noted an increase in the volume of trading in the Entity's securities over this period.

In light of the price change and increase in volume, ASX asks you to respond separately to each of the following questions:

1. Is the Entity 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?

In responding to this question, please consider in particular whether the Entity is aware of any information that its earnings for the 6 month period ended on 31 December 2013:

- a) are likely to differ materially (downwards or upwards) from any earnings guidance it has given for the period; or
- b) if the Entity has not given any earnings guidance for the period, are otherwise likely to come as a surprise to the market (by reference to analyst forecasts for the period or, if the Entity is not covered by analysts, its earnings for the prior corresponding period)?
- 2. If the answer to question 1 is "yes":
  - a) Is the Entity relying on Listing Rule 3.1A not to announce that information under Listing Rule 3.1?

Please note that the recent trading in the Entity's securities would suggest to ASX that such information may have ceased to be confidential and therefore the Entity 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.

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).

- c) If an announcement cannot be made immediately, why not and when is it expected that an announcement will be made?
- 3. If the answer to question 1 is "no", is there any other explanation that the Entity may have for the recent trading in its securities?
- 4. Please confirm that the Entity is in compliance with the Listing Rules and, in particular, Listing Rule 3.1.

#### 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 (ie. before 9.30 AM. AEDT) on 5 February 2014. If we do not have your response by then, ASX will have no choice but to consider suspending trading in the Entity'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, the Entity'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 kate.kidson@asx.com.au. It should <u>not</u> 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 Rule 3.1

Listing Rule 3.1 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. Exceptions to this requirement are set out in Listing Rule 3.1A.

The obligation of the Entity to disclose information under Listing Rules 3.1 and 3.1A is not confined to, nor is it necessarily satisfied by, answering the questions set out in this letter.

In responding to this letter, you should have regard to the Entity's obligations under Listing Rules 3.1 and 3.1A and also to Guidance Note 8 *Continuous Disclosure: Listing Rules 3.1–3.1B*.

## Trading halt

If you are unable to respond to this letter by the time specified above, or if the answer to question 1 is "yes" and an announcement cannot be made immediately, you should discuss with us whether it is appropriate to request a trading halt in the Entity'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 by electronic means without signature

Kate Kidson

Principal Adviser, Listings Compliance (Melbourne)