



Admedus Limited
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9 May 2017

Ms Anjuli Sinniah
Adviser, Listings Compliance (Perth)
ASX Compliance Pty Ltd
Level 40, Central Park
152-158 St Georges Terrace
PERTH WA 6000

Dear Ms Sinniah

ADMEDUS LIMITED (COMPANY) (AHZ): ASX AWARE QUERY

1. We refer to ASX's letter to the Company dated 5 May 2017 in relation to the ASX aware query (**ASX Letter**), as enclosed with this letter.
2. The ASX Letter requests that the Company respond to a number of questions relating to the grant by the FDA US Food & Drug Administration (**FDA**) of CardioCel® 3D 510(k) (**FDA Grant**).

BACKGROUND

3. On 10 February 2014, the Company announced that it had received FDA clearance to market CardioCel® in the US.
4. On 28 February 2017, the Company hosted a webinar following its half year results release, in which it, amongst other things, outlined its plans and expected time lines for CardioCel® 3D. This included noting that the product would be submitted as a special 510(k) submission ("manufacturing change") in April 2017 and first human use, pre-launch, was expected in June 2017.
5. On 26 April 2017, the Company released its Appendix 4C Quarterly Report in which it noted that the Company had lodged its FDA submission for its CardioCel® 3D product and that it anticipated that that would be approved later in the year.
6. The FDA Grant process is an administrative as opposed to a technical approval (as is the case for the FDA clearance process) and is essentially an extension of the Company's existing FDA clearance. The FDA Grant process typically takes up to 30 days, whereas the previous FDA clearance process typically takes approximately six months. The Company expected that the FDA Grant would be approved and had disclosed that expectation to the market (as detailed in paragraph 5).
7. The Company does not consider that the FDA Grant of CardioCel® 3D itself, as opposed to the previous CardioCel® FDA clearance, is information that a reasonable person would expect to have a material effect on the price or value of its securities, particularly given that the market was already aware that the Company was applying, and expected to receive, that grant within the timeframe that it was in fact received and that key expected timings and deliverables remained consistent with earlier Company announcements on 28 February and 26 April 2017.

ANALYSIS OF SHARE TRADING

8. At 6:37am (WST) on Monday, 1 May 2017, the Company lodged an unrelated announcement on the ASX Market Announcement Platform entitled: 'Admedus HSV-2 Phase IIa Results Webinar'. This announcement informed the market that the Company would be hosting an investor webinar to present the results of the HSV-2 program.
9. As noted in paragraph A of the ASX Letter, on Monday, 1 May 2017 the Company's share price rose from \$0.325 to \$0.365. The Company notes that it not unusual for the share price of bio-companies to increase in anticipation of results being released. The Company further notes that it observed speculation in the market as to what the results of its HSV-2 program would be, including on forums such as Hot Copper.
10. An analysis by the Company of the trades that occurred in its shares on Monday, 1 May 2017 revealed that there was a large volume of relatively small individual trades. This is consistent with speculative trading in anticipation of the Company releasing the results of the HSV-2 program.
11. Following the ASX announcement by the Company pre-market open on Tuesday, 2 May 2017, the Company's share price closed that day at approximately 38 cents (up mildly 2 cents).
12. On Thursday, 4 May 2017 the Company released the results of the HSV-2 program to ASX. At close of trading on that day the Company's share price had dropped 18.4% to approximately 31 cents. This again is consistent with speculative traders selling shares in the Company following the HSV-2 program results not being as positive as they had anticipated.

RESPONSE TO QUESTIONS IN ASX LETTER

13. The Company responds to each of the questions set out in the ASX Letter as set out below.

Question 1 - Does AHZ consider the FDA Grant to be information that a reasonable person would expect to have a material effect on the price or value of its securities?

14. For the reasons detailed above, the Company does not consider that the FDA Grant itself is information that a reasonable person would expect to have a material effect on the price or value of its securities.

Question 2 - If the answer to question 1 is "no", please advise the basis for that view.

15. Refer to above.

Question 3 - If the answer to question 1 is "yes", when did AHZ first become aware of the FDA Grant?

16. N/A

Question 4 - If the answer to question 1 is "yes" and AHZ first became aware of the FDA Grant before the date of the Announcement, did AHZ make any announcement prior to the Announcement 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 AHZ was obliged to release the information under Listing Rules 3.1 and 3.1A and what steps AHZ took to ensure that the information was released promptly and without delay.

17. N/A

Question 5 - Please confirm that AHZ is in compliance with the Listing Rules and, in particular, Listing Rule 3.1.

18. Confirmed.

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

19. Confirmed.

Yours sincerely,

A handwritten signature in black ink that reads 'M. McGuire'.

Mrs Maja McGuire
Company Secretary



5 May 2017

Maja McGuire
Company Secretary
26 Harris Road
MALAGA WA 6090

By email: mmcguire@admedus.com

Dear Ms McGuire,

Admedus Limited (“AHZ”): Aware Query

ASX Limited (“ASX”) refers to the following:

- A. The increase in AHZ’s share price from a close of \$0.325 on 28 April 2017 to a close of of \$0.365 on 1 May 2017.
- B. The FDA US Food & Drug Administration online database which discloses on the 510(k) Premarket Notification page that the CardioCel 3D 510(k) was granted on 28 April 2017 (“FDA Grant”).
- C. AHZ’s announcement entitled “Admedus Receives FDA Clearance for CardioCel 3D” lodged on the ASX Market Announcements Platform and released at 08:47 am on 2 May 2017 (the “Announcement”), disclosing AHZ received the FDA Grant to market CardioCel3D in the United States.
- D. 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.
- 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."

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

1. Does AHZ consider the FDA Grant 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 question 1 is "no", please advise the basis for that view.
3. If the answer to question 1 is "yes", when did AHZ first become aware of the FDA Grant?
4. If the answer to question 1 is "yes" and AHZ first became aware of the FDA Grant before the date of the Announcement, did AHZ make any announcement prior to the Announcement 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 AHZ was obliged to release the information under Listing Rules 3.1 and 3.1A and what steps AHZ took to ensure that the information was released promptly and without delay.
5. Please confirm that AHZ is in compliance with the Listing Rules and, in particular, Listing Rule 3.1.
6. Please confirm that AHZ'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 AHZ 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, 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 7.30 a.m. AWST) on Tuesday 9 May 2017**. If we do not have your response by then, ASX will have no choice but to consider suspending trading in AHZ'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, AHZ'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 anjuli.sinniah@asx.com.au and tradinghaltspert@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 AHZ’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 AHZ’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 AHZ’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]

Anjuli Sinniah
Adviser, Listings Compliance (Perth)