

17 March 2016

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

By email

Dear Sandra

ResApp Health Limited ("Company" or "ResApp") - ASX Aware Query

We refer to ASX's letter dated 15 March 2016 regarding the ASX aware query ("**Aware Letter**") and ASX letter dated 11 March 2016 regarding the ASX price and volume query ("**Price Letter**").

An overview of the relevant background and prevailing circumstances, which includes our responses to the questions in the Aware Letter, are set out below.

For ease of reference, at the end of this letter, we have included details of ASX's questions and a summary of our response.

Previous Announcements Regarding Pre-Submission Meeting with the FDA

The Company has made a number of announcements that have stated that it was due to hold a pre-submission meeting with the United States Food and Drug Administration ("**FDA**") during the first quarter of 2016 ("**Meeting**"). Refer to the following ASX announcements released by the Company:

- 31 December 2015 (ResApp Files Pre-Submission Package with the US FDA);
- 22 January 2016 (ResApp to Exhibit at Digital Healthcare Conference Dubai); and
- 17 February 2016 (Investor Presentation)

The Company has also announced to the market various milestones or "road maps" of key events that the Company believes are required to take place for FDA approval of the first ResApp product. Refer to the following ASX announcements released by the Company:

- 16 September 2015 (Investor Presentation);
- 11 November 2015 (US Roadshow - Investor Presentation);
- 25 November 2015 (CEO Presentation at Canary Networks Investor Roadshow); and
- 17 February 2016 (Investor Presentation).

Consequently, the fact that a pre-submission meeting was due to take place was not new information.

ResApp Health Limited ABN 51 094 468 318

Level 24, 44 St Georges Tce, Perth WA 6000

T +61 8 6211 5099 E info@resapphealth.com.au W www.resapphealth.com.au

For personal use only

Announcement Regarding Signing of Non-Binding MOU with Leading Humanitarian Organisation

On 7 March 2016, the Company announced that it had signed a non-binding memorandum of understanding ("**MOU**") to enter into a partnership to field test ResApp's smartphone-based pneumonia diagnostic tool in the developing world.

The Company notes that the closing price of its shares on ASX on Friday, 4 March 2016 (the last trading day prior to announcement of the signing of the MOU) was \$0.175. On the day of, and the days following, the announcement of the signing of the MOU, the closing price of the Company shares on ASX was:

- \$0.18 (7 March 2016);
- \$0.175 (8 March 2016);
- \$0.185 (9 March 2016);
- \$0.235 (10 March 2016); and
- \$0.27 (11 March 2016).

US Roadshow During The Period 1 March to 11 March 2016

During the period Tuesday, 1 March to Friday, 11 March 2016, the Company's CEO and Managing Director, Dr Tony Keating, was in the US for a series of presentations to US investors, partners and potential clinical collaborators.

Meeting with the FDA - Friday, 11 March 2016 Australian time (Thursday, 10 March 2016 US time)

On Friday, 11 March 2016 at 6:00am EDST (Thursday, 10 March 2016 at 2:00pm US EST), Dr Tony Keating attended the Meeting in Washington DC. The Meeting was also attended by another member of ResApp's management team, ResApp's scientific advisor (via phone from Australia), two representatives of Experien Group ("**Experien**") (the Company's FDA regulatory consultants) and a number of delegates from the FDA.

The Meeting lasted for approximately one hour, finishing at approximately 7:00am EDST Friday, 11 March (3:00pm US EST Thursday, 10 March).

Pre-submission meetings with the FDA are a largely consultative process. The FDA does not make any formal or definitive decision during such meetings. Generally, the FDA provides feedback on planned activities to be undertaken by an organisation in relation to obtaining FDA approval for a product.

In attending the Meeting, the Company did not expect to receive any formal decision in relation to the proposed process directly from the FDA.

Following the Meeting, the Company consulted with Experien, and its scientific adviser, to clarify their interpretation of the comments and feedback provided by the FDA at the Meeting. Senior management of the Company also discussed the feedback provided by Experien, the Company's scientific adviser and the FDA over the weekend of 12 and 13 March 2016.

For personal use only

It was agreed on Sunday, 13 March 2016 that the Company would not be materially changing its regulatory approval strategy or planned clinical trials, which had previously been announced to the market. Refer to the following ASX announcements released by the Company:

- 16 September 2015 (Investor Presentation);
- 11 November 2015 (US Roadshow - Investor Presentation);
- 25 November 2015 (CEO Presentation at Canary Networks Investor Roadshow); and
- 17 February 2016 (Investor Presentation).

ASX Price and Volume Query - Friday 11 March 2016

At 8:14am (WST) on Friday, 11 March 2016, the Company received the Price Letter from ASX.

In its response to the Price Letter ("**Response Letter**"), the Company noted that it had announced its entry into the MOU on 7 March 2016 and that it believed the announcement had been well received by the market, resulting in increased trading in the Company's securities.

The Response Letter also noted that Dr Keating had been in the US in the past week presenting to a number of investors, partners and potential clinical study collaborators. In addition, the Response Letter stated that the Meeting had been held at 2:00pm (US EST) on Thursday, 10 March 2016 (being 6:00am Sydney time Friday, 11 March 2016), and noted that, as previously announced to the market, this pre-submission meeting was to take place in the current quarter to discuss the Company's regulatory pathway to FDA approval.

Dr Keating's Return from the US

Dr Keating left Washington DC at 5:15pm on Friday, 11 March 2016 (US EST) (9:15am on Saturday, 12 March Australia EDST), arriving back in Brisbane on Sunday, 13 March at 7:15am Australia EDST. On Sunday, 13 March, Dr Keating participated in discussions with other members of the Company's board, which determined that the Company would not be materially changing its regulatory approval strategy or planned clinical trials.

Preparation and Release of Announcement in Relation to Meeting

The announcement relating to the Meeting ("**Announcement**") was prepared over the course of the weekend of 12 and 13 March, once the Company had sufficient time to digest the comments from the FDA, Experien and the Company's scientific adviser, and once the Company's directors had determined that there would be no material change to the Company's existing regulatory approvals strategy and planned clinical trials. The Announcement was submitted to ASX by the Company pre-market open on Monday, 14 March 2016 and released to the market by ASX at 9:29am (EDST) on the same date.

Responses to Specific Questions in the Aware Letter

1. Please advise when the Entity first became aware of the outcome of the pre-submission meeting with the FDA (the "**Outcome**").

The Company believes it is incorrect to say that there is a clear regulatory "outcome" from the Meeting. Refer to the statements under the heading "Pre-Submission Meeting with the FDA", which indicate that pre-submission meetings with the FDA are largely consultative and designed to provide feedback on an organisation's planned activities to obtain FDA approval. The FDA does not make any definitive or formal decision of an applicant's regulatory approvals strategy at such meetings. Consequently, the Company does not believe there is any regulatory "outcome" from the Pre-Submission Meeting.

The statement in the Announcement of a "positive outcome" is the Company's interpretation of the feedback it received at Meeting and is based on management's and the board's interpretation as well as Experien's feedback on comments made by the FDA at the Meeting. As a result of the comments from the FDA, Experien and the Company's scientific adviser, the Company's directors determined that there would be no material change to the Company's existing regulatory approvals strategy and planned clinical trials for the purpose of seeking FDA approval of ResApp's first product.

2. Does the Entity consider the Outcome to be information that a reasonable person would expect to have a material effect on the price or value of its securities?

No. Given that there is no formal regulatory "outcome" of the Meeting, there is no "outcome" which is information that a reasonable person would expect to have a material effect on the price or value of the Company's securities.

The Company does not believe the actual holding of the Meeting is information that a reasonable person would expect to have a material effect on the price or value of the Company's securities either. The fact the Company was due to have a pre-submission meeting with the FDA is information that has been in the public domain for some time. Refer to the statements above under the heading "Previous Announcements Regarding Pre-Submission Meeting with the FDA".

The Company does not believe that its interpretation of the FDA's feedback at the Meeting is information that a reasonable person would expect to have a material effect on the price or value of the Company's securities. The feedback received at the Meeting led the Company's directors to conclude that the Company would not be materially changing its existing regulatory approvals strategy and planned clinical trials for the purposes of obtaining FDA approval of the first ResApp product. Information regarding the Company's strategy and process, in relation to the FDA approval pathway, has been in the market since at least 16 September 2015. Refer to the announcements under the heading "Previous Announcements Regarding Pre-Submission Meeting with the FDA".

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

Refer to the response to 2 above.

For personal use only

4. If the answer to question 2 is "yes" and the Entity first became aware of the Outcome prior to the release of the Announcement, did the Entity make any announcement prior to the release of the Announcement which disclosed the Outcome? 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 the entity was obliged to release the information under Listing Rule 3.1 and 3.1A and what steps the Entity took to ensure that the information was released promptly and without delay.

Not applicable.

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

The Company confirms that it is in compliance with the Listing Rules and, in particular, Listing Rule 3.1.

Yours sincerely



Nicki Farley
Company Secretary

For personal use only



15 March 2016

Ms Nicki Farley
Company Secretary
ResApp Health Limited

By email: nicki@tridentms.com.au

Dear Ms Farley

ResApp Health Limited (the “Entity”): ASX aware query

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

1. The recent change in the price of the Company’s securities from a closing price of \$0.18 on Monday, 7 March 2016 to an intra-day high of \$0.26 on Friday, 11 March 2016 and a substantial increase in the volume traded over this period.
2. The price query letter from ASX dated 11 March 2016 in which ASX queried the recent increased price and volume movement in the Entity’s securities.
3. The Entity’s response to the price query letter dated 11 March 2016 (“Response to ASX”) in which the Entity stated, among other things, that the Entity’s Managing Director, Dr Tony Keating held a pre-submission meeting with the FDA at 2pm (US EST) on Thursday, 10 March 2016 (being 6am EDST, 11 March 2016).
4. The Entity’s announcement entitled “ResApp Completes Successful Pre-Submission Meeting with the US FDA” lodged with ASX Market Announcements Platform and released at 09:29 am (EDST) Monday, 14 March 2016 (the “Announcement”), disclosing a positive outcome from the Entity’s recent pre-submission meeting with the United States Food and Drug Administration (“FDA”) regarding its diagnostic mobile software application, ResAppDx. The Announcement states, among other things, that during the meeting the Entity received targeted feedback from the FDA regarding the proposed US regulatory pathway, clinical study protocols, planned non-clinical evaluations and data requirements.
5. 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.
6. The definition of “aware” in Chapter 19 of the Listing Rules. This definition 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

For personal use only



possession of the information in the course of the performance of their duties as an officer of that entity.”

Additionally, you should refer to section 4.4 in Guidance Note 8 *Continuous Disclosure: Listing Rules 3.1 – 3.1B “When does an entity become aware of information”*.

7. 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 requirements 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.”

5. 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 “Listing Rule 3.1A.2 – the requirement for information to be confidential”*. 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, we ask that you answer the following questions in a format suitable for release to the market in accordance with Listing Rule 18.7A:

1. Please advise when the Entity first became aware of the outcome of the pre-submission meeting with the FDA (the “Outcome”).



2. Does the Entity consider the Outcome 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. If the answer to question 2 is “yes” and the Entity first became aware of the Outcome prior to the release of the Announcement, did the Entity make any announcement prior to the release of the Announcement which disclosed the Outcome? 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 the entity was obliged to release the information under Listing Rules 3.1 and 3.1A and what steps the Entity took to ensure that the information was released promptly and without delay.
5. 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 **3.00 p.m. WST on Thursday, 17 March 2016**. 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 Sandra.Wutete@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 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, 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 electronically without signature]

Sandra Wutete
Senior Adviser, Listings Compliance (Perth)