



# Proteomics International

LABORATORIES LTD

14 June 2017

ASX Compliance Pty Ltd  
Level 40 Central Park  
152-158 St George's Terrace  
PERTH WA 6000  
Attn: Mr Mauro Piccini

by email: [mauro.piccini@asx.com.au](mailto:mauro.piccini@asx.com.au)

Dear Mr Piccini

## AWARE LETTER

We acknowledge receipt of ASX's letter dated 13 June 2017 regarding the change in price of the Company's securities from a closing price of \$0.16 on Thursday, 8 June 2017, to an intra-day high of \$0.20 on Friday, 9 June 2017, the trading halt request released on Friday, 9 June 2017 (**Trading Halt Request**) and the announcement entitled "Clinical validation study confirms PromarkerD performance" released on Tuesday, 13 June 2017 (**Announcement**) (**ASX's Letter**).

In response to each of your questions, we advise as follows:

1. The Company confirms that it considers the information in the Announcement to be information that a reasonable person would expect to have a material effect on the price or value of its securities.
2. Not applicable.
3. The data analysis and internal interpretation of the clinical validation study for the PromarkerD test for diabetic kidney disease was completed by the Company at 2pm on Thursday 1 June 2017. However, final interpretation and announcement of results from the clinical validation study was subject to publication of the prior predictive clinical development study.
4. On 4 April 2017, an announcement entitled "PromarkerD Update" was released to ASX (**PromarkerD Update**). The PromarkerD Update outlined in detail the studies completed to date and expected timing of publication of results from those studies.

As disclosed in the PromarkerD Update, the Company's policy is to present test results for peer-review through publication in a medical journal or presentation at a scientific meeting as part of the validation process. The Board's view, having regard to the *Code of Best Practice for Reporting by Life Science Companies (Second Edition)*, is that disclosure of results before peer review to independently prove the findings is premature and without publication, key opinion leaders are less likely to consider the results from the Company's studies credible.

By way of example, the Company announced the results from the PromarkerD diabetic kidney disease diagnostic test study in an announcement entitled “Diabetic Kidney Disease Diagnostic Test Data Published” which was released on 8 February 2017 following publication on that day of the study in the peer-reviewed scientific journal *EuPA Open Proteomics*, the official journal of the European Proteomics Association (**EuPA**).

Subsequently, and as outlined in the PromarkerD Update, the Company submitted the predictive test data from the clinical development study for peer-review by the American Diabetes Association. As noted in the PromarkerD Update, the time required for peer review of the predictive test data delayed the Company’s ability to finalise interpretation of the data and release further results from its follow up validation clinical study.

In the interim, the Company presented its initial predictive test results at leading conferences hosted by the International Diabetes Federation, Australian Diabetes Society and Proteomics Society of India and continued this strategy to raise key opinion leader awareness and acceptance of the technology.

On 5 April the Company was advised that the results of its clinical development study may be presented at the American Diabetes Association’s 77<sup>th</sup> Annual Scientific Sessions to be held from 9 to 13 June 2017 in San Diego, USA. The Company was informed by the American Diabetes Association that results would be released to delegates at the conference on Saturday, 10 June 2017 under strict embargo.

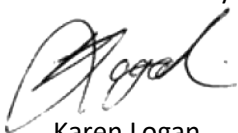
As a result of this peer-review process, the Company was able to finalise interpretation of the data from the follow-up clinical validation study and immediately submitted (1 June 2017) the results to the American Diabetes Association to be combined with the clinical development study. These results were automatically accepted for joint release, subject to the same strict embargo.

The Company considered its continuous disclosure obligations and in particular, timing of release of the results to the ASX and concluded that as the clinical validation results were being presented at a conference in the USA over the long weekend in Australia, the results would be released at the earliest possible opportunity once the Company was able to confirm that the results were in fact published by the American Diabetes Association, being prior to the market open on Tuesday, 13 June 2017.

Notwithstanding the fact that all necessary precautions were taken to ensure the results of the clinical validation study would be released as scheduled at the conference on Saturday, 10 June 2017 in the USA, the Company requested a trading halt of its securities on Friday, 9 June 2017 as a precautionary measure.

5. The Company confirms that, to its best knowledge and belief, it is in compliance with ASX Listing Rules and in particular, Listing Rule 3.1.
6. The Company confirms that these responses to ASX’s Letter have been authorised and approved by the Board in accordance with its published continuous disclosure policy.

Yours sincerely

A handwritten signature in black ink, appearing to read 'K Logan', with a stylized flourish at the end.

Karen Logan  
Company Secretary



13 June 2017

Ms Karen Logan  
Company Secretary  
Proteomics International Laboratories Ltd  
Level 1, Office F, 1139 Hay Street  
WEST PERTH WA 6005

By email: [karen.logan@themiscorporate.com](mailto:karen.logan@themiscorporate.com)

Dear Ms Logan

**PROTEOMICS INTERNATIONAL LABORATORIES LIMITED ("COMPANY") – AWARE LETTER**

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

- A. The change in the price of the Company's securities from a closing price of \$0.16 on Thursday, 8 June 2017, to an intra-day high of \$0.20 on Friday, 9 June 2017.
- B. The Company's trading halt request released on the ASX Market Announcements Platform ("Platform") at 08:58am AWST on Friday, 9 June 2017 ("Trading Halt Request").
- C. The Company's announcement entitled "Clinical validation study confirms PromarkerD performance" released on the Platform at 07:32 am AWST on Tuesday, 13 June 2017 ("Announcement"), disclosing that results from its validation clinical study show that the PromarkerD blood test can predict the onset of diabetic kidney disease better than any current measure.
- 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 the following:

*“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 the Company to answer separately each of the following questions and provide the following confirmations in a format suitable for release to the market in accordance with Listing Rule 18.7A.

1. Does the Company consider the information in the Announcement (“Information”) 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. When did the Company first become aware of the Information? In answering this question, please specify the date and time when the Company first became aware of the Information or any part thereof.



4. If the Company first became aware of the Information before the Trading Halt Request, did the Company make any announcement prior to the relevant date which disclosed the Information? If so, please provide details. If not, please explain why the Information was not released to the market at an earlier time, commenting specifically on when you believe the Company was obliged to release the Information under Listing Rules 3.1 and 3.1A and what steps the Company took to ensure that the Information was released promptly and without delay.
5. Please confirm that the Company is in compliance with the Listing Rules and, in particular, Listing Rule 3.1.
6. 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.

#### **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 pm AWST on Friday, 16 June 2017**. If we do not have your response by then, ASX will have no choice but to consider suspending trading in the Company'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 Company'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 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. 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 Platform.

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

In responding to this letter, you should have regard to the Company'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 the Company'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 the Company'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*.

Please contact me if you have any queries about the above.

Yours sincerely

*[sent electronically without signature]*

Mauro Piccini  
**Senior Adviser, ASX Listings Compliance**