



Proteomics International

LABORATORIES LTD

16 February 2021

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

by email: ListingsCompliancePerth@asx.com.au

Dear Mr Nicholson,

PRICE AND VOLUME QUERY

We acknowledge receipt of ASX's letter dated 16 February 2021 regarding a change in the price of the Company's shares from \$0.82 on Tuesday, 9 February 2021 to a high of \$1.075 on Tuesday, 16 February 2021, and increased trading volumes during that period (**ASX's Letter**).

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

1. The Company is not 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.
2. Not applicable.
3. The Company acknowledges that the price increase was from a low of \$0.82 to a high of \$1.075 but notes that Proteomics International has had similar changes in price and increased volumes following release of the announcement of publication on 15 June 2020 of the results of the first stage 3,000-patient study undertaken in collaboration with a global top 20 pharmaceutical company, as well as announcement on 12 November 2020 of the second distribution agreement for its PromarkerD predictive test in the Middle East.

Proteomics International considers that the increase in price and trading volume are a result of a combination of factors, including:

- (a) Proteomics International announced in an ASX release dated 8 February 2021 that it has filed a pre-submission package to the United States Food and Drug Administration (FDA) for the PromarkerD test, the world's first predictive diagnostic test for diabetic kidney disease. This consultative process will help Proteomics International determine the best regulatory path forward for PromarkerD, being either the De Novo Classification or 510(k) routes. FDA approval will enable broad-scale deployment of the simple, low-cost blood test in the US,

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where there are more than 30 million people with diabetes. PromarkerD already has CE Mark in the European Union.

- (b) Proteomics International released its Appendix 4C - December 2020 Quarterly Report together with a Quarterly Activities Report on 28 January 2021, which provided an update on its business activities for the three months to December 2020, including:
- (i) The signing of the first and second distribution agreements for the PromarkerD immunoassay test in Italy and Israel, and continued discussions with various prospective partners.
 - (ii) Continued engagement with Key Opinion Leaders (KOL) and regulatory and reimbursement bodies in a number of jurisdictions in relation to the PromarkerD test.
 - (iii) Market engagement studies through specialised consultants addressing:
 - Economic Health Benefit (Payer Budget Impact study) for insurers/payers
 - Clinical Utility (Decision Impact study) for test adoption by health professionals.
 - (iv) Publication of three studies in internationally peer-reviewed journals *Clinical Proteomics*, *Proteomes* and the *Journal of Clinical Medicine*, being an international validation study and additional clinical assay performance results for the PromarkerD test.
 - (v) The Promarker pipeline of diagnostic R&D activities, including the partnership with the QIMR Berghofer Medical Research Institute to develop a simple blood test to improve detection of oesophageal adenocarcinoma, the most common form of oesophageal cancer in Australia.
 - (vi) Completion of a heavily oversubscribed placement of A\$6.0 million in which UK and Australian-based institutions, sophisticated and professional investors participated, and which significantly strengthened the Company's balance sheet (at 31 December 2020, the Company had cash reserves of \$7.54 million), providing capital to drive the delivery of the PromarkerD test in major global markets, future licensing deal negotiations and assist in accelerating the diagnostic pipeline.
- (c) As disclosed in recent announcements, the Company has a number of significant near-term commercial and operational milestones to be achieved for PromarkerD, specifically:
- Manufacture and up-scaling of reagent inventory for the PromarkerD predictive test in the northern hemisphere;
 - Publication of results of the second stage 3,000-patient study undertaken in collaboration with a global top 20 pharmaceutical company;
 - Regulatory and reimbursement pathways for PromarkerD in a number of jurisdictions; and
 - Further licensing and distribution agreements.
- (d) The COVID-19 pandemic has given rise to increased market and community awareness of the importance of diagnostic testing which appears to be contributing to the recent re-rating of the junior healthcare sector.
- (e) A number of diagnostic companies in the Company's peer group in Australia and globally have had significant share price appreciations in recent months.
4. 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.

5. The Company confirms that these responses to ASX's Letter have been authorised and approved by the Managing Director and Chairman under delegated authority from the Board to respond to ASX on disclosure matters.

Yours sincerely,

Karen Logan
Company Secretary



16 February 2021

Reference: 30955

Ms Karen Logan
Company Secretary
Proteomics International Laboratories Limited

By email

Dear Ms Logan

Proteomics International Laboratories Limited ('PIQ'): Price and Volume - Query

ASX refers to the following:

- A. The change in the price of PIQ's securities from a low of \$0.82 on Tuesday, 9 February 2021, to an intraday high of \$1.075 at the time of writing, today.
- B. The increase in the volume of PIQ's securities traded from 9 February 2021 to 16 February 2021.

Request for information

In light of this, ASX asks PIQ to respond separately to each of the following questions and requests for information:

- 1. Is PIQ 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?
- 2. If the answer to question 1 is "yes".
 - (a) Is PIQ relying on Listing Rule 3.1A not to announce that information under Listing Rule 3.1? Please note that the recent trading in PIQ's securities would suggest to ASX that such information may have ceased to be confidential and therefore PIQ 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 PIQ may have for the recent trading in its securities?
- 4. Please confirm that PIQ is complying with the Listing Rules and, in particular, Listing Rule 3.1.
- 5. Please confirm that PIQ's responses to the questions above have been authorised and approved under its published continuous disclosure policy or otherwise by its board or an officer of PIQ 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 Listing Rule 18.7. Your response is required as soon as reasonably possible and, in any event, by no later than **2:15 PM AWST Tuesday, 16 February 2021**. 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, PIQ'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 and may require PIQ to request a trading halt immediately.

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

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 PIQ'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 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*.

Suspension

If you are unable to respond to this letter by the time specified above, ASX will likely suspend trading in PIQ's securities under Listing Rule 17.3.

Listing Rules 3.1 and 3.1A

In responding to this letter, you should have regard to PIQ'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 PIQ'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.

Release of correspondence between ASX and entity

We reserve the right to release a copy of this letter, your reply and any other related correspondence between us to the market under Listing Rule 18.7A.

Questions

If you have any questions in relation to the above, please do not hesitate to contact me.

Yours faithfully

Daniel Nicholson
Adviser, Listings Compliance (Perth)