Proteomics International
LABORATORIES LTD

ASX Release
29 April 2021

ASX code: PIQ

Proteomics International files US FDA 513(g) regulatory submission

- **513(g) application will allow Proteomics International to determine the best product classification and FDA regulatory path for PromarkerD**
- **Application replaces pre-submission package filed in February, after the FDA limited this pathway to urgent applications only due to the COVID-19 pandemic**
- **FDA is expected to provide feedback within 60 days**
- **Projected timelines to a full FDA application and subsequent commercialisation remain unaffected**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) has filed a 513(g) submission to the United States Food and Drug Administration (FDA) for its PromarkerD test for diabetic kidney disease.

The application replaces the pre-submission package lodged with the FDA in February [ASX: 8 February], after the regulatory body took the unprecedented step of limiting the pre-submission route to urgent applications only due to the COVID-19 pandemic.

The FDA advised the Company that it is unable to conduct an in-depth review of the pre-submission due to its current COVID-19 related resource limitations. However, other review pathways remain open, and consequently Proteomics International has closed its pre-submission and replaced it with the 513(g) request.

As with pre-submission, the 513(g) application will allow Proteomics International to determine the best regulatory path for PromarkerD - either the De Novo Classification or 510(k) route. The main difference from the pre-submission is that clinical data is not required in 513(g) requests.

The FDA is expected to assess the application and provide feedback on the applicable regulatory pathway within 60 days. The Company is preparing to file a full application under either pathway in Q3 CY21, in line with previously stated timeframes.

Proteomics International managing director Dr Richard Lipscombe said, *"The suspension of the detailed pre-submission pathway was understandable, and FDA's response to a 513(g) request will provide the information we need for the next steps in obtaining market clearance for PromarkerD in the US. We look forward to working closely with the FDA despite the ongoing pandemic, and we continue to expand our marketing activities in the US and beyond as we address this next regulatory step."*

Authorised by Dr Richard Lipscombe (Managing Director) on behalf of the Board of PIQ.

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About PromarkerD (www.PromarkerD.com)
PromarkerD is a predictive test for the early detection of chronic kidney disease (CKD) in patients with type-2 diabetes. CKD is one of the major complications arising from diabetes and if unchecked can lead to dialysis or kidney transplant.

The patented PromarkerD test system uses a simple blood test to detect a unique 'fingerprint' of the early onset of disease by measuring three serum protein biomarkers, combined with three routinely available conventional clinical variables (age, HDL-cholesterol and estimated glomerular filtration rate (eGFR)).

In clinical studies published in leading journals PromarkerD correctly predicted 86% of otherwise healthy diabetics who went on to develop chronic kidney disease within four years. The PromarkerD immunoassay, the PromarkerD mass spectrometry assay, and the PromarkerD software hub have each achieved CE Mark registration in the European Union.

Further information is available through the PromarkerD web portal.

To visit the PromarkerD virtual booth please see: www.PromarkerD.com/product

About Proteomics International Laboratories (PILL) (www.proteomicsinternational.com)
Proteomics International (Perth, Western Australia) is a wholly owned subsidiary and trading name of PILL (ASX: PIQ), a medical technology company at the forefront of predictive diagnostics and bio-analytical services. The Company specialises in the area of proteomics – the industrial scale study of the structure and function of proteins. It received the world's first ISO 17025 laboratory accreditation for proteomics services, and operates from state-of-the-art facilities located on Perth's QEII Medical Campus.

Proteomics International's business model is centred on the commercialisation of the Company's world-leading test for diabetic kidney disease, PromarkerD. The Company offsets the cash burn from R&D and product development through provision of specialist analytical services, whilst using its proprietary Promarker™ technology platform to create a pipeline of novel diagnostic tests.

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