Proteomics International
LABORATORIES LTD

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Proteomics International seeks FDA approval for PromarkerD

- **Pre-submission package for diabetic kidney disease (DKD) test lodged with the US Food and Drug Administration (FDA)**
- **Proteomics International expected to meet with the FDA to progress clearance within 10 weeks**
- **FDA pre-submission follows CE Mark regulatory approval for PromarkerD in Europe**
- **Globally there are 463 million adults living with diabetes, including 31 million in the US**
- **The Covid-19 pandemic has increased public awareness of the importance of diagnostic testing but caused a backlog in diagnostic services for other serious illnesses such as DKD - an issue that healthcare systems and diagnostic companies are now looking to address**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), a pioneer in predictive diagnostics, is pleased to announce that it has filed a pre-submission package to the United States Food and Drug Administration (FDA) for the PromarkerD test for diabetic kidney disease.

The Company is seeking additional regulatory approval for the easy-to-use 'kit' version of PromarkerD, the world's first predictive diagnostic test for diabetic kidney disease. PromarkerD already has CE Mark in the European Union. FDA approval will enable broad-scale deployment of the simple, low-cost blood test in the US, where there are more than 30 million people with diabetes.

FDA pre-submission allows manufacturers of innovative diagnostics and medical devices to discuss specific aspects of the regulatory process and requirements with FDA experts. 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. Proteomics International is expected to meet with the FDA to progress clearance within 10 weeks.

PromarkerD uses a unique protein 'fingerprint' to predict the onset of diabetic kidney disease (DKD) up to four years before clinical symptoms appear. Accurately diagnosing at-risk type-2 diabetics allows physicians to provide treatment plans with the aim of slowing or even halting the kidney disease. Chronic kidney disease is one of the major complications arising from type-2 diabetes, which if left unchecked can lead to dialysis or kidney transplant, and costs the US healthcare system $130 billion per year in Medicare spending alone.[1]

Proteomics International will present the FDA with robust, peer-reviewed clinical performance data demonstrating the effectiveness of the test, including a 3,000-patient study undertaken in collaboration with a global top 20 pharmaceutical company.

[1] United States Renal Data System - https://adr.usrds.org/2020

Feedback from the pre-submission will provide valuable insights into what the Company will need to provide to make the approval process run as efficiently and timely as possible. FDA industry guidance suggests early interaction with the regulatory body may improve the quality of subsequent submissions, shorten total review times, and facilitate the development process for new devices.

Proteomics International managing director Dr Richard Lipscombe said FDA approval would be a significant commercialisation milestone for PromarkerD. *"FDA sign off would assure potential licensing partners and consumers that the test has been developed and manufactured to US safety, health and environmental protection standards. With CE Mark approval and FDA clearance we would have access to more than 70 per cent of the global IVD diagnostic market."*

Dr Lipscombe stated further, *"We are also seeing increased public awareness of the importance of diagnostic testing due to the Covid-19 pandemic, and diagnostic companies globally have received significant funding to enhance their testing capabilities. These companies are now looking to address the backlog in diagnosing other chronic diseases that has arisen due to the pandemic. We know that of these, diabetic kidney disease is one of the most prevalent and costly to deal with. Progression towards FDA approval for PromarkerD aligns well with US diagnostic companies looking to broaden the suite of tests they offer."*

In addition to the kit technology, PromarkerD can be made available to US patients as a laboratory developed test (LDT) ahead of FDA approval. Proteomics International is in advanced discussions with a number of diagnostic groups exploring this parallel route to market.

Authorised by the Board of Proteomics International Laboratories Ltd (ASX.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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