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# Proteomics International

LABORATORIES LTD

## **Proteomics signs collaboration agreement with US big pharma to accelerate diabetic kidney disease & heart disease drug discovery using PromarkerD**

- Proteomics International and Janssen Research & Development, LLC have signed a collaboration agreement to use PromarkerD predictive capabilities in diabetic kidney disease drug discovery
- PromarkerD is the world's first commercial test for predicting the onset of diabetic kidney disease
- Joint study to test the performance of PromarkerD in predicting decline in kidney function and drug response in patients from Janssen's completed clinical trials
- There are currently 425 million adults globally with diabetes, which can lead to the life-threatening complications of cardiovascular disease and kidney disease
- Collaboration will also evaluate PromarkerD in the new area of predicting heart disease which is a major cause of death in patients with diabetes
- PromarkerD test has already been licensed in USA, Mexico, Dominican Republic, and Spain

Medical technology company Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), which has pioneered the world-leading predictive diagnostic test for diabetic kidney disease, PromarkerD, announces it has signed a research collaboration agreement with Janssen Research & Development, LLC (Janssen, [www.janssen.com](http://www.janssen.com)), for diabetic kidney disease treatment research.

*"Using PromarkerD predictive technology to accelerate drug discovery is an exciting development with significant applications globally. We are pleased to be working with one of the largest pharma companies to support rapid treatment development for diabetic kidney disease,"* said Dr Richard Lipscombe Proteomics International Managing Director.

The collaborative study between Proteomics International and Janssen combines a shared interest in improving kidney outcomes in people with diabetes.

Under the agreement Janssen will provide samples from its completed clinical trials and Proteomics International will perform the sample testing, with joint analysis of the study results. Both parties will bear their own costs, with the cost to Proteomics International being fully budgeted and classified as R&D for tax purposes. The analysis is expected to take 6-12 months at which point the results will be published.

The collaborative study will use PromarkerD as an early predictor of kidney function in patients who took part in Janssen's clinical trials, and assess how the PromarkerD score correlates with drug response in patients with diabetic kidney disease. The drug is of the gliflozin (SGLT-2 inhibitor) class that helps lower blood sugar in adults with diabetes.

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The collaboration will also evaluate how PromarkerD performs in predicting heart disease, another major complication arising from diabetes. Diagnosis of cardiovascular risk would be a new application for PromarkerD.

Globally there are 425 million adults with diabetes and already one in three have diabetic kidney disease. Those with diabetes are also more than twice as likely to die from heart disease than those without.

*"Gliflozin drugs could be hugely beneficial in improving patient outcomes from diabetes complications and we look forward to determining whether PromarkerD can help in assessing responses to this treatment",* said Dr Lipscombe.

Two weeks ago Proteomics International announced the completion of production of the immunoassay kit version of the PromarkerD test [ASX: 9 November 2018] and presented performance verification results at the 18th Annual Diabetes Technology Meeting in North Bethesda, USA.

The world-first test for predicting the onset of diabetic kidney disease was recently licensed as a mass spectrometry "Laboratory Developed Test" (LDT) to PHDx for launch in the USA. It is due to launch in Mexico and Spain in the New Year.

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#### **About PromarkerD ([www.PromarkerD.com](http://www.PromarkerD.com))**

PromarkerD is a predictive diagnostic test for diabetic kidney disease. In clinical studies presented at the American Diabetes Association Annual Scientific Sessions [ASX: 10 June 2017] and published in the prestigious journal Diabetes Care [ASX: 6 September 2017], PromarkerD correctly predicted 86% of otherwise healthy diabetics who went on to develop chronic kidney disease within four years.

More recent results presented at the 18th Annual Diabetes Technology Meeting [ASX: 9 November 2018] show the PromarkerD protein biomarkers vastly outperform both existing diagnostic tests (albumin creatinine ratio "ACR" urine test, and estimated glomerular filtration rate "eGFR" blood test) in predicting future diabetic kidney disease, with adjusted odds ratio (OR)=1.98 (95%CI 1.31-3.01) versus OR=1.16 (0.94-1.42) and OR=0.87 (0.85-0.90), respectively.

PromarkerD has been rated the world's leading diagnostic test for diabetic kidney disease by the global research house Frost & Sullivan in its report titled Biomarkers Enabling Diabetes and Obesity Management [ASX: 27 March 2017]. PromarkerD has received patent protection in several major jurisdictions including the USA, China, Europe, and Japan, with others pending.

Further information is available through the PromarkerD web portal.

#### **About Janssen Research & Development**

For further information see [www.janssen.com](http://www.janssen.com)

#### **About Proteomics International Laboratories (PILL) ([www.proteomicsinternational.com](http://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. Proteomics International's business model is centred on the commercialisation of the company's world-leading test for diabetic kidney disease, PromarkerD, whilst using its proprietary Promarker™ technology platform to create a pipeline of novel diagnostic tests, and offset the cash burn from R&D and product development through provision of specialist analytical services.

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