



# Proteomics International

LABORATORIES LTD

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## Proteomics International expands study with US big pharma

- Proteomics International and Janssen Research & Development, LLC expand their collaboration involving PromarkerD and diabetic kidney disease drug discovery
- The study is testing the performance of PromarkerD in predicting decline in kidney function and treatment response in patients from a Janssen completed clinical trial
- Results of the first phase of work have been accepted for presentation at the world's leading diabetes conference, the 80<sup>th</sup> Scientific Sessions of the American Diabetes Association (ADA)
- There are considered to be 463 million adults living with diabetes and currently 1 in 3 have diabetic kidney disease
- The additional phases of work to determine how PromarkerD risk scores change with treatment are likely to report in Q2/Q3 CY2020

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) is pleased to announce its collaboration with Janssen Research & Development, LLC (Janssen) targeting diabetic kidney disease (DKD) treatment is progressing well and will now be expanded, with the initial findings to be presented at the world's leading diabetes conference.

Results of the first phase of work have been accepted for presentation at the 80<sup>th</sup> Scientific Sessions of the American Diabetes Association (ADA) and remain under embargo until 13<sup>th</sup> June 2020.

The collaborative study, which commenced in November 2018, is testing the performance of PromarkerD in predicting decline in kidney function and drug response in patients from a Janssen completed clinical trial [ASX: 26 November 2018]. The studies involve Proteomics International's scientific team working with Janssen scientists firstly to validate the effectiveness of PromarkerD as a DKD predictive diagnostic test across a large patient group, and then to ascertain the relationship of PromarkerD to treatment. Other cardiovascular measures are being investigated as an ongoing point of interest.

Dr Richard Lipscombe, Managing Director of Proteomics International said, *"We are excited to announce the expansion of the existing collaboration with Janssen, and are particularly pleased to be co-presenting the findings of the first stage of our studies at the world's preeminent diabetes conference, the 80<sup>th</sup> Scientific Sessions of the American Diabetes Association."*

### **Collaboration Expansion**

Determining a direct relationship between PromarkerD and patient outcomes is a complex process with extensive data analysis required over the large clinical data set. Janssen and Proteomics International have now agreed to extend the collaboration to examine the PromarkerD score in patient samples after treatment to assess if patients display an improved prognosis, i.e. does their

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PromarkerD risk score decrease. The collaboration is due to continue until November 2020, with both parties to continue to bear their own costs.

Significantly, samples will be tested using the new higher throughput PromarkerD immunoassay, PromarkerD (IA) instead of the mass spectrometry platform, PromarkerD (MS). Use of PromarkerD (IA) may provide important results to support Proteomics International's future FDA regulatory applications.

The additional clinical samples are currently being shipped to Proteomics International's Perth laboratories and will be analysed over the next 2-3 months. Statistical analysis will then be performed on the data, a task expected to take 1-2 months.

### ***Statistical Analysis and Clinical Application of PromarkerD***

The understanding of diabetic kidney disease continues to evolve as greater focus is placed on the importance of combating this debilitating disease. In particular, Proteomics International is focused on accurately characterising the initial phases of DKD, due to the fact there are several different definitions of early kidney decline currently in use in clinical practice.

The large datasets contained in the Janssen clinical trial combined with Proteomics International's published clinical cohort (the Fremantle Diabetes Study) are enabling this critical transition point to be explored. Examining the important subtleties in the results has prolonged the statistical analysis due to the rich amount of data yielded by the collaboration.

In parallel with the new work the on-going statistical analysis seeks to optimise the performance of PromarkerD and enable its use against the broadest possible range of definitions of kidney decline to maximise the clinical utility of the test.

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

ENDS

#### **# Definitions:**

"Promarker" - the proprietary technology used to discover and evaluate proteins for use as diagnostics

"PromarkerD/PromarkerD test system" - the patented predictive diagnostic test for Diabetic Kidney Disease

"PromarkerD (MS)" - the predictive diagnostic test for Diabetic Kidney Disease using Mass Spectrometry

"PromarkerD (IA)" - the predictive diagnostic test for Diabetic Kidney Disease using ImmunoAssay

"PromarkerD Hub" - the proprietary software tool used to calculate the risk of Diabetic Kidney Disease in diabetes patients

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

The PromarkerD test system assesses the risk of diabetic kidney disease (DKD) in patients with type 2 diabetes. Chronic kidney disease is one of the major complications arising from diabetes and if unchecked can lead to dialysis or kidney transplant. PromarkerD is a simple blood test that uses a unique protein 'fingerprint' to provide an early detection of the onset of disease. 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.

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. 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

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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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