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Proteomics International

LABORATORIES LTD

Clinical validation study confirms PromarkerD can predict diabetic kidney disease better than any current measure

- PromarkerD test predicted 86% of previously disease-free patients who went on to develop chronic kidney disease within four years
- Study is the largest prospective clinical study on diabetic kidney disease in the community and evaluated 792 patients over a four year period
- Results presented at the American Diabetes Association's 77th Annual Scientific Sessions in the Late-breaking Abstracts section of the conference, 9-13th June 2017, San Diego
- If unchecked, the International Diabetes Federation predicts the 'at risk' population will be 642 million by 2040, and the number of diabetics with chronic kidney disease will rise by 76 million to 214 million
- In March 2017, Frost & Sullivan identified PromarkerD as the world's leading test for diabetic kidney disease
- PromarkerD has the potential to save healthcare systems around the world billions of dollars in costs associated with treating diabetic kidney disease
- Commercialisation of the test proceeding which has the potential to deliver substantial revenues to PIQ in the form of licensing fees and royalties

San Diego, June 10th - Proteomics International Laboratories Ltd (ASX: PIQ) (PILL) announced results from its validation clinical study showing that the PromarkerD blood test can predict the onset of diabetic kidney disease better than any current measure. These findings were presented by Professor Tim Davis, from The University of Western Australia Medical School, at the American Diabetes Association's 77th Annual Scientific Sessions (ADA), 9-13th June, in San Diego, California.

The study, undertaken as a joint collaboration between Proteomics International and The University of Western Australia, is the largest prospective clinical study on diabetic kidney disease in the community and evaluated the clinical utility of PromarkerD with 792 patients. In March, Frost & Sullivan identified PromarkerD as the world's leading test for diabetic kidney disease, and the new results confirm PromarkerD predicts rapid decline in kidney function in type 2 diabetes, across clinically significant definitions of disease, independently of recognised clinical risk factors.

According to the International Diabetes Federation, 415 million adults had diabetes in 2015. The US Center for Disease Control states that one in three adult diabetics have chronic kidney disease, or 138 million people today. Once detected, chronic kidney disease can be treated through medication and lifestyle changes to slow down the disease progression, and to prevent or delay the onset of kidney failure. The International Diabetes Federation further predicts the number of diabetics will rise to 642 million by 2040, which, if unchecked, will increase the number of adults with chronic kidney disease by 76 million to 214 million. The current cost of dialysis is estimated at \$100,000 per person per year.

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The validation study (assessing the performance of the prediction model in an independent population) confirms results from the original development study, also completed in collaboration with Professor Davis. Initial findings on the diagnostic performance of PromarkerD were published in the European Journal of Proteomics in March 2017.

In the four-year prospective study, the three protein marker (biomarker) blood test (PromarkerD) predicted 86% of previously disease-free patients who went on to develop chronic kidney disease (Sensitivity 86%, Specificity 78%, AUC 0.88). In comparison to the development study the results from the larger validation study showed slightly lower levels of predictive ability (development 95%), however, achieved a 10% improvement in levels of false positives.

Professor Davis concluded “The data supports the use of the protein biomarker panel in conjunction with eGFR (estimated glomerular filtration rate) in patients with type 2 diabetes to monitor and predict their decline in kidney function.”

“This large clinical study validates the important role of the PromarkerD test to effectively monitor patients with diabetes,” said Dr Richard Lipscombe, Managing Director of Proteomics International. “Although patients may appear to be adequately controlled for the complications of diabetes, current tests do not reveal early symptoms of kidney disease, which can result in the need for dialysis or kidney transplant.”

The annual ADA Scientific Sessions are the world’s largest and most prominent meeting of diabetes experts, attracting more than 13,000 delegates. The results were reported in the Late-breaking Abstracts section of the conference, titled “Novel Circulating Biomarkers Predicting Rapidly Declining Renal Function in Type 2 Diabetes: The Fremantle Diabetes Study”. PILL’s head of business development Chuck Morrison also attended the event.

PromarkerD - a predictive diagnostic test for diabetic kidney disease (www.PromarkerD.com)

PromarkerD is a breakthrough blood test that uses a protein ‘fingerprint’ to measure kidney disease in patients with diabetes. This ground-breaking test can both diagnose and predict disease.

A published study in a peer-reviewed journal has shown that for diabetic patients already suffering from chronic kidney disease PromarkerD can diagnose the presence of disease that was missed by the current gold standard tests (known as the ACR and eGFR tests).

Critically, PromarkerD can also predict the onset of disease before clinical symptoms appear. In the current study 792 patients were followed in dual, four-year longitudinal clinical studies. PromarkerD correctly predicted 86% of the previously kidney disease-free diabetic patients who went on to develop chronic kidney disease.

The Frost & Sullivan report titled “Biomarkers Enabling Diabetes and Obesity Management” is available via PILL’s website (www.proteomicsinternational.com).

Milestone	2017			
	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec
Key patents secured and extended	✓			
Diagnostic test data published	✓			
Independent market research report		✓		
Predictive test clinical study results published			■	
Clinical validation study results announced		✓		
Prototype kit manufacture complete			■	
First commercial sales targeted				■

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PILL continues to make progress towards the commercialisation of the PromarkerD test as shown in the table above. The results from the validation study reinforce the Company's belief that by identifying and treating people at risk of developing DKD before symptoms appear, many lives will be saved as well as billions of dollars in health care costs.

PILL's vision is for PromarkerD to become a flagship test which dramatically improves the outcomes of people with a high risk of developing chronic kidney disease.

ENDS

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The Fremantle Diabetes Study (FDS)

The Fremantle diabetes Study is a longitudinal observational study of a community-based, urban population in Fremantle, Western Australia. The study, which commenced in 1993 with a more recent phase II in 2008, contains over 3,000 recruits, and is headed by Professor Tim Davis of Fremantle Hospital and the Medical School at The University of Western Australia.

The strengths of the FDS are the inclusive and representative nature of the cohorts, the range and detail of data collection and linkage to well-established morbidity and mortality databases. The design and implementation of the FDS means that specific questions regarding the natural history of diabetes, its impact on the individual and its costs can be addressed with relative rigour.

The University of Western Australia

Ranked in the world's top 100 universities, The University of Western Australia (UWA) is Western Australia's first university and has an international reputation for excellence in education, research and community engagement. The University is located alongside the Swan River, five kilometres from the heart of Perth city. UWA's cutting-edge research attracts high levels of competitive research funding and researchers who are global leaders in their field.

Proteomics International Laboratories (PILL) (www.proteomicsinternational.com)

Proteomics International is a wholly owned subsidiary and trading name of PILL (ASX: PIQ), a medical technology company focused on proteomics – the industrial scale study of the structure and function of proteins. In the last few years, proteins have become the drug class of choice for the pharmaceutical industry because of their intimate role in biological systems. Thus proteomics technology is now playing a key role in understanding disease, from finding new diagnostic biomarkers to determining drug targets, and discovering new biopharmaceutical drugs.

PILL is recognised as a global leader in the field of proteomics. It received the world's first ISO 17025 laboratory accreditation for proteomics services, and operates from state-of-the art facilities at the

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Harry Perkins Institute of Medical Research in Perth, Western Australia. The company's business model harnesses its proprietary technology platform to work across three integrated areas, each massive growth markets:

- 1. Diagnostics:** Biomarkers of disease and personalised medicine - focus on diabetic kidney disease.
By 2020 the biomarkers market is estimated to double in size to \$45.6 billion, and the personalised medicine market is forecast to be worth over \$149 billion.
- 2. Analytical services:** Specialist contract research fee-for-service model – focus on biosimilars QC.
The global biosimilars market is expected to reach \$6.2 billion by 2020, almost trebling from its 2015 level, as it seeks to replicate the multiple billion dollar blockbuster drugs that are coming off patent.
- 3. Drug discovery:** Therapeutic peptide drug discovery - focus on painkillers and antibiotics.
The global peptide therapeutics market is currently estimated to be worth \$18 billion and is expected to increase by over 10% per year during 2016-2025.

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