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Proteomics International
LABORATORIES LTD

## Proteomics announces further positive results from clinical study:
# PromarkerD shows improved predictive ability and robustness

Proteomics International Laboratories Ltd (ASX: PIQ) (PILL) is pleased to provide an update on its clinical studies for PromarkerD, the company's breakthrough test for the prediction of diabetic kidney disease. These results will be presented today at the International Conference on Functional and Interaction Proteomics: Application in Food and Health, in New Delhi, India, which is being hosted by the Proteomics Society of India.

- PromarkerD predicts diabetic kidney disease across all major clinical definitions of rapid decline in kidney function
- Predictive ability improved - PromarkerD correctly predicted 61-97% of individuals[1] who went on to have a clinically significant decline in kidney function within four years
- Inter-laboratory study shows robustness of PromarkerD as a future Laboratory Developed Test (LDT)

There are currently 415 million adults worldwide with diabetes[2], and approximately one-third of these people have chronic kidney disease which can lead to dialysis or kidney transplant.

Further analysis of the original four year clinical study data has confirmed 10% of patients experienced a rapid decline in their kidney function when measured according to a variety of definitions of kidney function decline. Refinement of the PromarkerD algorithm has enabled 61-97% (84% on average) of these people to be predicted up to 4 years in advance.

PromarkerD uses a fingerprint of three proteins found in the blood in combination with simple clinical data to predict which patients will experience a decline in kidney function in the future. There is currently no available test for predicting the onset of diabetic kidney disease.

PromarkerD was developed in a $2 million clinical study in collaboration with the University of Western Australia Medical School, which followed 576 patients with diabetes for four years (the “development” study). PILL has subsequently embarked on a follow-up study using an independent patient group with data collected between 2010 and 2016 in Western Australia (the “validation” study). The current validation study brings the total number of patients studied to more than 1000.

As part of the validation study a small subset of samples were provided to the Mass Spectrometry Core Facility at the University of Sydney to undertake an inter-laboratory comparison. Using a related but different technology platform the new data showed excellent reproducibility (between the two laboratories the assay average coefficient of variation was 11.9%, against a target of 15%).

Proteomics International managing director Dr Richard Lipscombe said we could not have hoped for much more from these analyses. “The improved sensitivity in our preferred definition of kidney

1 Value dependent on the clinical definition of “rapid decline” in kidney function (See Development Study table of results)
2 International Diabetes Federation: Diabetes Atlas 2015

decline and the broad applicability across other definitions indicates PromarkerD is a robust test, whilst the inter-laboratory study is an important step in proving the effectiveness of PromarkerD as a future LDT", he said.

**Clinical Background**

Statistical analysis of the two studies has been complicated by the multiple definitions of decline in kidney function used in clinical settings. This is a direct consequence of existing tests having limitations in diagnosing the disease condition.

There are two current gold standard diagnostic tests — a urine test (measuring the albumin creatinine ratio "ACR"), and a blood test (measuring serum creatinine which is used to estimate glomerular filtration rate "eGFR"). Doctors cannot always agree which test to use, and neither test can predict if patients are likely to develop the condition in the future.

The ground-breaking results announced in 2015 used eGFR decline trajectories as an innovative means to define rapid kidney decline and establish the biomarker panel in the development study.

PILL has now analysed the effectiveness of PromarkerD against three additional definitions of rapid kidney function decline considered clinically significant, including those recommended by leading health organisations including the US Food and Drug Administration (FDA) and the Kidney Disease: Improving Global Outcomes (KDIGO) 2012 guidelines.

These definitions include: incident (new onset) chronic kidney disease (CKD) (defined as an eGFR less than 60mL/min/1.73m$^2$ after four years, in patients who were free from kidney disease at the start of the study), a decline in eGFR of more than 30 per cent over four years, and a decline of more than 5mL/min/1.73m$^2$/year over four years.

**Statistical Analysis**

Across each clinical definition approximately 10 per cent of the patient group developed a clinically significant decline in kidney function over the course of the study.

Across all four definitions, PromarkerD was able to correctly predict which patients would have a clinically significant decline in kidney function with 72.5% accuracy. In PILL's preferred definition "incident chronic kidney disease" the test correctly predicted up to 95% of affected patients.

In addition to being able to predict which patients will see a decline in kidney function, the PromarkerD biomarker panel can be used to diagnose the early stages of diabetic kidney disease where the ACR and eGFR tests for kidney function fail to detect the condition.

Further results of the validation study will be available in the first quarter of 2017.

| **DEVELOPMENT STUDY** | | |
|---|---|---|
| Definition of Kidney Function Decline | Sensitivity | Specificity |
| eGFR trajectory | 84% | 82% |
| Incident CKD (eGFR<60) | 95% | 68% |
| eGFR decline >30% (4 yr) | 97% | 62% |
| eGFR decline >5ml/yr (4 yr) | 61% | 73% |

Note: Sensitivity is also known as the true positive rate; Specificity is a measure of the false positive rate (e.g. 82% specificity equals 18% FPR); Accuracy is the percentage of correct diagnoses [(true positives plus true negatives)/total number of patients]

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**About Proteomics International Laboratories (PILL)**

PILL (ASX: PIQ) is 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 Harry Perkins Institute of Medical Research in Perth, Western Australia. The Company's business model uses its proprietary technology platform 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 at over 10% per year during 2016-2025.

In combination these areas offer, respectively, medium term products, near term cash flow, and blue sky potential by harnessing one complementary workflow centred on proteins.