



# Proteomics International

LABORATORIES LTD

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## PromarkerD Update

- **Follow up, validation study on 500 patient cohort underway – results to be announced in due course.**
- **Company is instigating its own development program to produce a standard clinical pathology In vitro Diagnostic (IVD) test kit for PromarkerD.**
- **PILL to present to key bio-analytical sector decision makers at invitation only events in the USA this week.**

Life sciences company Proteomics International Laboratories Ltd (ASX: PIQ) (the Company, PILL) is pleased to provide the following market update on PromarkerD, the world's first proteomics-derived predictive (prognostic) test for the diagnosis of Diabetic Kidney Disease.

### Partnering and Licensing Progress

PILL remains in ongoing discussions with a number of diagnostic and pharmaceutical companies in global markets, including USA, Europe, Japan and Latin America, for the commercialisation of PromarkerD. As part of this process, PILL has been in discussion with a major global health care company (potential partner) for a period of 11 months in relation to the partnering and licensing of PromarkerD. These discussions continue to progress in a positive manner.

As part of this process, the potential partner requested follow-up validation studies of PromarkerD to confirm its initial ground-breaking results (ASX announcement, 9 June 2015). The initial results were produced from a clinical study of 576 patients with diabetes.

PILL now advises it is undertaking a new study on an independent cohort of 500 patients with diabetes. Its aim is to apply the Company's established predictive model (algorithm) to further validate PromarkerD, and in parallel, advance its application as a Laboratory Developed Test (LDT). Both studies use patients from the Fremantle Diabetes Study in Western Australia, one of the largest on-going diabetes studies globally.

As part of this validation study PILL will also undertake a cross-centre analysis on these samples, utilising an independent third-party laboratory and different types of instrumentation. The results of the follow up study will be announced in due course.

The Company's potential partner is also in the process of providing an additional international patient study cohort, with the aim of demonstrating the robustness of PromarkerD across different geographical regions. PILL will also provide results of this study when they become available.

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## Development Update

PILL is also pleased to advise that it will now embark on its own development pathway for PromarkerD with the ultimate end-goal of developing a commercial-ready clinical pathology In vitro Diagnostic (IVD) test kit for PromarkerD.

The Company has commenced the process to source antibodies needed for a multiplex ELISA (Enzyme-linked immunosorbent assay), which is the precursor to an IVD test. It has also commenced discussions with an assay development company, with a proprietary multiplex ELISA platform, to develop the assay on its platform. PILL is excited about the prospects of its PromarkerD IVD development program and will update the market on its progress in due course.

In undertaking its own development pathway for PromarkerD as an IVD test kit, in conjunction with ongoing partnering and licensing discussions, PILL now has multiple, complementary commercialisation pathways for PromarkerD as a Laboratory Developed Test (LDT), standard clinical pathology IVD test and Companion Diagnostic (CDx). The Company continues to work with Newsummit Biopharma Co to commercialise PromarkerD in China.

## Marketing

Complementing the above activities, PILL continues to market PromarkerD in major global markets. This week, managing director Dr Richard Lipscombe will present PromarkerD to key bio-analytical sector decision makers at invitation only events in Boston, San Francisco and San Diego, in the USA. The focus of the presentation will be a case study on the benefit of biomarkers in the pharmaceutical development process.

The events are being hosted by leading global drug development services company inVentiv Health Clinical, and PILL will be one of only two presenting companies. PILL's global head of business development Chuck Morrison will also attend the events and he and Dr Lipscombe will take the opportunity to advance on-going discussions with potential partners for PromarkerD.

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### **About Proteomics International Laboratories (PILL)**

PILL is an ASX listed (ASX: PIQ) life science company focused on the area of proteomics – the industrial scale study of the structure and function of proteins. Proteomics is an integral part of the biotechnology and life sciences industries and plays a key role in understanding disease and biological systems.

PILL is recognised as a global leader in its field. 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 which operates across three synergistic areas, each massive growth markets:

- 1. Diagnostics:** Biomarkers of diseases and personalised medicine - focus on diabetic kidney disease and Alzheimer's disease. The biomarkers market is estimated to double in size to \$45.6 billion by 2020.
- 2. Analytical services:** Specialist contract research, analytical testing and consultancy - fee for service model. The specialist proteomics market alone represents a massive global market estimated to be worth \$20.8 billion by 2018.
- 3. Drug discovery:** Therapeutic drug discovery with a focus on painkillers and antibiotics. The peptide therapeutics market is currently estimated to be worth \$17 billion.

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