



Proteomics International

LABORATORIES LTD

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PromarkerD kit version completed and ready for imminent commercial release

- PromarkerD is the world's first commercial test for predicting the onset of diabetic kidney disease
- Production of the new PromarkerD kit completed and first commercial batches to ship on 20 November, 2018
- The new PromarkerD immunoassay kit can be used by pathology laboratories globally, expanding the addressable market for PromarkerD significantly
- More licensing deals expected as the PromarkerD immunoassay kit opens up further commercialisation opportunities in Japan, India, and around the world
- Positive verification results on the PromarkerD immunoassay kit will be presented today at the 18th Annual Diabetes Technology Meeting, North Bethesda, USA
- There are currently 425 million adults globally with diabetes, and one in three already have diabetic kidney disease which may have been preventable by PromarkerD testing
- PromarkerD could save the US healthcare system alone up to USD100 billion per year in direct costs associated with treating end-stage kidney disease
- PromarkerD mass spectrometry "Laboratory Developed Test" (LDT) has already been licensed in USA, Mexico and Spain

Medical technology company Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) announces the first commercial batches of the new PromarkerD immunoassay kit will be shipped on 20 November following positive performance verification results being presented at the international summit, Diabetes Technology (8-10 November, 2018, North Bethesda, Maryland).

First commercial launch of the new PromarkerD immunoassay kit

The first commercial batches of the kit are due to ship on 20 November, 2018. This follows completion of production of the key antibody reagents in Puerto Rico, and manufacture of the kit in certified facilities in California, both instigated in partnership with licence partner Omics Global Solutions.

The PromarkerD kit will be used to target new commercialisation deals in Japan and India, opening the door to further commercialisation discussions around the world.

The PromarkerD mass spectrometry "Laboratory Developed Test" (LDT) has already been licensed in USA, Mexico and Spain. The LDT permits fast adoption of a new test in advanced markets and is being used to build market demand prior to wider release of the PromarkerD kit.

The world-first test for predicting the onset of diabetic kidney disease was recently licensed to PHDx (Austin, Texas) for launch in the USA. It is also due to launch in Mexico and Spain in the New Year.

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Verification results presented at the 18th Annual Diabetes Technology Meeting

The Diabetes Technology Meeting is for technology developers and users to facilitate the creation of new and cost-effective tools to help people with diabetes.

The new PromarkerD kit results are featured in an Abstract entitled "PromarkerD: A Novel Test for Predicting Rapid Decline in Renal Function in Type 2 Diabetes" reference number PETE1899D, and will be presented today, 9 November.

The results further validate the performance of PromarkerD and its power in predicting kidney decline, which is not possible with the existing diagnostic tests (ACR and eGFR).

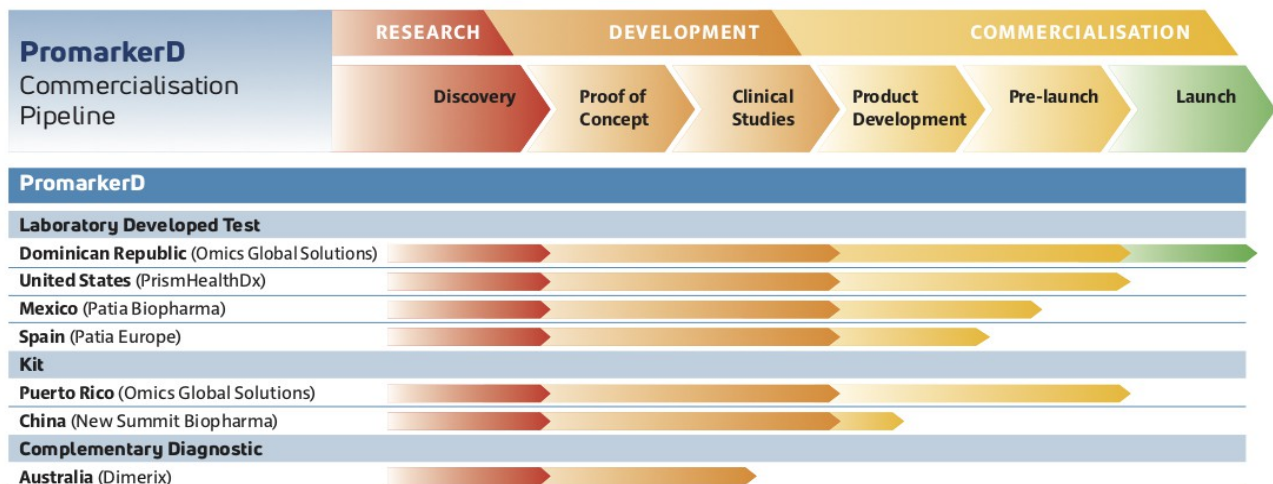
The kit version uses an immunoassay format (also known as an in vitro diagnostic or IVD) and can be used in pathology labs around the world, subject to regulatory approval.

Proteomics International's partner Omics Global Solutions (Puerto Rico, USA) will be the first to use the new kit through its distributor in the Dominican Republic, Macrotech Farmacéutica, the exclusive provider of dialysis services in the country.

Proteomics International Managing Director Dr Richard Lipscombe said:

"Diabetes and diabetes associated diseases are a major global health problem that put an ever increasing burden on the health sector. PromarkerD could save the US healthcare system up to USD100 billion per year in direct costs associated with treating end-stage kidney disease."

"We are delighted that the results of the PromarkerD Kit have been accepted for presentation at the 18th Annual Diabetes Technology Meeting. This shows the power of the Promarker™ technology platform and what Proteomics International is doing in the field of predictive testing for global diseases".



The PromarkerD commercialisation pipeline and typical timeline is as follows:
 Discovery (3-6 months), Proof of concept (3-6 months), Clinical studies (12 months), Product development (9-18 months), Pre-launch (3-6 months)

ENDS

About the PromarkerD study for the 18th Annual Diabetes Technology Meeting

Results presented at the 18th Annual Diabetes Technology Meeting 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

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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.

As recommended by the Clinical and Laboratory Standards Institute guidelines, PromarkerD scores were measured using the mass spectrometry platform (LDT) and immunoassay (IVD kit) tests in 100 patients with type 2 diabetes. Data from the two tests was used to estimate risk of future diabetic kidney disease, and showed the risk estimates from the two tests were highly correlated (correlation coefficient = 0.989).

About PromarkerD (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.

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 Proteomics International Laboratories (PILL) (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 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, 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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