



Proteomics International

LABORATORIES LTD

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PromarkerD immunoassay In Vitro Diagnostic test (IVD) platform successfully developed and validated

Highlights

- **Proteomics International successfully completes validation of its new advanced PromarkerD immunoassay In Vitro Diagnostic Test (IVD) platform**
- **Results of successful PromarkerD cross-platform validation study presented at the 18th Human Proteome Organization World Congress, Adelaide, 15-18 September**
- **The new PromarkerD IVD technology can be manufactured as either a kit or configured to run on automated immunoassay platforms allowing it to service the needs of a greater number of clinical diagnostics laboratories around the world**
- **Proteomics International now has two PromarkerD test technology platforms adaptable to the different needs of the diverse clinical testing market**
- **The advanced PromarkerD immunoassay opens the way to further commercialisation deals in USA, Japan, India and around the world**

Medical technology company Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) announces successful performance validation results for a new advanced PromarkerD immunoassay In Vitro Diagnostic Test (IVD). The PromarkerD test system will now be available using two technology platforms that can service the Laboratory Developed Test and the IVD markets.

Following several months pre-development, Proteomics International engaged specialist immunoassay developer TGR Biosciences (Australia) for the production of a new PromarkerD immunoassay for use in markets such as the USA and Australia. Importantly, the new PromarkerD IVD technology can be manufactured as either an immunoassay kit or can be configured to run on an automated machine platform, allowing the analysis of hundreds of blood samples at a time.

This is a major development milestone for the PromarkerD diabetic kidney disease test system and will enhance the ease of use of the test in laboratories around the globe.

The immunoassay has been designed using TGR Biosciences' advanced CaptSure™ technology platform [PIQ Annual Report: 30 Aug 2019]. This translates to a more efficient, faster, and simpler assay protocol than standard sandwich immunoassays, and complements the initial PromarkerD immunoassay [ASX: 9 Nov 2018] which is made by partner Omics Global Solutions (Puerto Rico) and marketed under licence as Innovatio ND2.

Last week Proteomics International announced two pivotal milestones in the commercialisation of PromarkerD with the launch of the mass spectrometry laboratory developed test (MS-LDT) in Spain through licence partner Patia Europe, which followed the completion of the technology transfer of the MS-LDT to the laboratories of molecular diagnostics partner Atturo.

Proteomics International Managing Director Dr Richard Lipscombe said it has been important to build test assays adaptable to the different needs of the diverse clinical testing market, and our

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immunoassay can be readily used in pathology laboratories around the world, subject to regulatory approval. “The completion of the IVD test complements the existing MS-LDT meaning that laboratories can use the test system that best suits the equipment of the laboratory and the specialist experience of their laboratory staff. This in turn will increase the attractiveness of PromarkerD in the diagnostics community which should accelerate the commercialisation of our ground breaking test,” he said.

The immunoassay validation follows a stringent cross-platform study to demonstrate data equivalence in 100 patient samples analysed against the mass spectrometry (MS-LDT) version of PromarkerD. The two technology platforms exhibited high correlation ($R=0.97$).

The results of this cross-platform validation study were presented overnight in the Disease Biomarkers, Assays and Diagnostic Proteomics section of the 18th Human Proteome Organization (HUPO) World Congress, Adelaide, 15-18 September 2019 (Abstract number 660: PromarkerD: A novel test for predicting rapid decline in renal function in type 2 diabetes).

TGR Biosciences will now complete stability studies on the IVD and then commence production of test packs of reagents for evaluation by potential licence partners.

Globally there were 425 million adults with diabetes in 2017, a global prevalence of 9.9% showing a dramatic rise from the 108 million adults with diabetes in 1980. Currently one in three adults with diabetes already have diabetic kidney disease, however, with early intervention it is possible to delay or prevent clinical symptoms of the disease.

Proteomics International is in discussions with tier-1 diagnostics and pharmaceutical companies, targeting the markets of Europe, Japan, India and the USA, to expand the global reach of PromarkerD.

About PromarkerD (www.PromarkerD.com)

The PromarkerD test system assesses the risk of diabetic kidney disease 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 [ASX: 10 Sept 2019]. PromarkerD has received patent protection in multiple jurisdictions including Europe, China, Japan and the USA.

Further information is available through the PromarkerD web portal.

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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. The Company’s business model uses its proprietary technology platform across three integrated areas of diagnostics, drug discovery and analytical services.

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