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Proteomics International signs deal with PrismHealthDx to launch PromarkerD predictive test for diabetic kidney disease in USA

Medical technology company Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) has signed the first licence agreement for the United States for its world-leading PromarkerD predictive test for diabetic kidney disease, creating a partnership with US-based precision medicine and diagnostic services laboratory PrismHealthDx, Inc. (PHDx).

Highlights

- USA PromarkerD launch targets the world's biggest spending country on diabetes care •
- World leading predictive test can save and extend lives by avoiding diabetic kidney disease •
- Test to be offered to patients through a partnership with precision medicine and diagnostic services laboratory PrismHealthDx, Inc. (PHDx)
- PHDx will launch the PromarkerD test nationally with a major marketing campaign •
- Potential to save US healthcare system billions of dollars in treatment and dialysis costs
- PromarkerD licensing discussions ongoing in Mexico, Australia, China, Japan, and Europe •

Proteomics International has granted PHDx, head-quartered in Austin, Texas, a licence for the clinical market in the USA to make PromarkerD available to the more than 30 million Americans living with diabetes.

The USA has one of the highest rates of diabetes in the world and is by far the biggest spending country on diabetes-related healthcare. Kidney disease is responsible for 48,000 deaths a year in the USA—the ninth leading cause of death—and related healthcare spending tops US\$50 billion a year.

Dialysis treatment alone costs US\$72,000 per person per year, according to the US Renal Data System. Diabetes accounts for 44 per cent of chronic kidney disease cases in the USA.

Proteomics International Managing Director Dr Richard Lipscombe said PromarkerD was a major weapon in the battle against the diabetes epidemic. "Regular testing and early diagnosis of diabetic kidney disease with PromarkerD can help millions of people avoid costly and invasive dialysis treatment or a kidney transplant," he said.

"We are very excited to launch this product nationally across the USA" said Jim Canfield, President and CEO of PHDx. "This revolutionary technology will complement PHDx's existing portfolio to create the leading diabetes test offering in the country. It will save lives and improve the quality of life for diabetes sufferers, all while reducing the cost to the healthcare system."

Under the national licence agreement PHDx will develop and commercialise the PromarkerD mass spectrometry "Laboratory Developed Test" (LDT) in its specialist certified laboratories. The LDT permits fast adoption of a new test in advanced markets. First sales are anticipated to be in four to six months, and Proteomics International will receive a royalty on all tests sold. Further details of the licence agreement are commercially sensitive and remain confidential.

PromarkerD is a simple blood test that uses a unique protein 'fingerprint' to detect signs of disease.

PromarkerD is the first test able to *predict* the onset of diabetic kidney disease, warning of a decline in kidney function up to four years in advance. The test can also *diagnose* diabetic kidney disease better than the current gold standard tests.

PromarkerD has the potential to spare millions of people from future dialysis costs, and save the US healthcare system hundreds of billions of dollars.

Ten percent of people living with diabetes are expected to suffer a rapid decline in kidney function within four years. The PromarkerD test is able to predict this decline in kidney function in 86 per cent of cases. If every one of the 30 million Americans with diabetes took the test it would potentially identify 2.6 million of the 3 million people on the path to kidney disease. Those identified would also require systematic retesting to verify effectiveness of treatments. As for any novel test, market penetration cannot be predicted accurately.

Dr Lipscombe said the breakthrough deal for PromarkerD in the USA is important because it paves the way for other licensing contracts. "It is great to see PromarkerD launching in the world's largest healthcare market as we further negotiations to commercialise the test in other countries including Mexico, Japan, Australia, China and Europe."

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About PromarkerD (www.PromarkerD.com)

PromarkerD is a predictive diagnostic test for diabetic kidney disease. In clinical studies presented in 2017 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 PHDx, Inc (www.phdxinc.com)

PrismHealthDx, Inc. (PHDx) is a precision medicine diagnostic laboratory and services company specialising in comprehensive biomarker testing to detect the onset of disease and serious medical conditions at their earliest and most treatable stage. PHDx provides a 'one-stop-shop' opportunity to integrate best-in-class laboratory and clinical medicine into practices, driving better clinical outcomes and helping to make an immediate difference in the lives of their patients. PHDx's management team has extensive experience in developing and commercialising novel assays and they are committed to advancing new diagnostic and disease management capabilities. PHDx works in partnership with academic leaders, industry leaders, and clinical providers.

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 bioanalytical 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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