



Proteomics International
LABORATORIES LTD

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PromarkerD

Predictive diagnostic test to launch in Q1 2018

Commercialisation and licensing remains on track for the world leading predictive diagnostic test for diabetic kidney disease, with diabetes costing global healthcare systems US\$825 billion per year.

Medical technology company Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), a leader in predictive diagnostics, is pleased to announce the official product launch of PromarkerD, its world leading predictive diagnostic test for diabetic kidney disease, will be 8 February 2018. The official launch represents the achievement of a key milestone in the stepped approach to commercialise the test in global markets.

- **The global cost of treating diabetes and its complications is US\$825 billion dollars a year**
- **422 million people have diabetes and 1 in 3 adult diabetics have chronic kidney disease**
- **Global launch of PromarkerD, the world leading predictive diagnostic test for diabetic kidney disease, will be in Feb 2018**
- **Manufacture completed of key components for the IVD version of PromarkerD**
- **Milestone payment for first commercial sales on target for Q1 2018**
- **Patents extended to all kidney disease in Australia; already granted in \$50 billion USA market**
- **Discussions ongoing with potential licensing partners in the USA, Mexico, Japan, Australia, China and Europe**

The test will be launched by Proteomics International's partner, Macrotech Farmacéutica, the exclusive provider of dialysis services in the Dominican Republic, and will conclude the primary production process for the in vitro diagnostic (IVD) version of the PromarkerD test.

The first commercial sale will trigger a milestone payment, then royalties on each test sold, as part of Macrotech Farmacéutica's exclusive licensing agreement which has a net present value of USD 1.5M over its first nine years. The Dominican Republic has a population of 10.6 million, with approximately 505,000 adults with diabetes. This compares to a diabetes incidence of approximately 1 million in Australia, 29 million in the USA, and 110 million in China, all markets in which Proteomics International has been granted patent protection and where the company is currently working on commercialisation of PromarkerD.

One in three people suffering from diabetes already have chronic kidney disease, with dialysis treatment in the USA costing US\$72,000 per person per year. Early detection with PromarkerD allows early intervention and may enable the onset of disease to be delayed or prevented altogether, with potentially dramatic savings for global healthcare systems.

Proteomics International is also focused on commercialising PromarkerD in the vibrant US market for specialist laboratory testing, so-called Laboratory Developed Tests (LDT) that are run by certified

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laboratories (ASX: 22 Nov 2017). The LDT permits fast adoption of a new test in advanced markets, whereas the IVD will follow a traditional regulatory process.

The use of dual technology platforms enables the roll out of the test tailored to respective markets. Both routes to market can attract upfront fees, milestone payments (e.g. at first sale) and royalties per test.

There are currently no approved drugs specifically for diabetic kidney disease, however there are 21 drugs in clinical trials for the condition. Consequently, another route to market for PromarkerD remains as a companion diagnostic test (CDx), whereby it is used to monitor patients during clinical trials to measure whether drugs are having a positive effect. According to the FDA a CDx provides information that is essential for the safe and effective use of a corresponding drug.

Discussions are ongoing with a number of potential partners to bring the PromarkerD test to market as an IVD, LDT, and/or CDx in mainland USA, Mexico, Japan, Australia, China and Europe.

As described in the PromarkerD Update of 4 April 2017, and the 2017 Annual Report, the targeted commercialisation milestones for PromarkerD are:

PromarkerD Milestones	2017-18			
	Jul-Sep	Oct-Dec	Jan-Mar	Apr-Jun
IP protection and KOL engagement				
Key patents secured and extended ¹	✓	✓		
Predictive test clinical study results published		✓		
IVD roll-out (Dominican Republic)				
Prototype kit manufacture complete	-- -- --	-- ✓		
First commercial sales of IVD		--	■	
Milestone payment for first commercial sales			■	
Licensing				
First licensing deal/partnership for LDT		--	■	
First licensing deal/partnership for CDx			■	
Second licensing deal for IVD				■

¹ Patents for DKD were first granted in the USA, Singapore and Australia in 2015, and in China and Russia in 2016; other jurisdictions remain pending. An expansion of the PromarkerD patent to all kidney disease was granted in the USA in August, and in Australia in November (see below).

-- Original target | ✓ Completed

Patents extended to all forms of kidney disease

All people with or at risk of diabetes represent potential users of PromarkerD. In addition, the test may be used to diagnose all forms of kidney disease, which would further increase the size of the addressable market. In the United States 30 million people suffer from chronic kidney disease, with currently 44% of cases attributed to diabetes. Medicare spending for patients with chronic kidney disease aged 65 and older exceeded US\$50 billion in 2013, and represented 20% of all Medicare spending in this age group.

Further research is required to prove the effectiveness of PromarkerD for all kidney disease, nonetheless, Proteomics International is pleased to announce Australian patent number 2015202230, titled “Biomarkers associated with kidney disease” was granted on the 16th November 2017. A similar patent has already been granted in the USA.

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The manufacturing process explained

The PromarkerD test kit assembly is currently being completed in the US territory of Puerto Rico, which has become one of the world's biggest centres for pharmaceutical manufacturing as well as medical devices and supplies. Despite the impact of Hurricane Maria only five weeks production time was lost, and the safety systems operated by the manufacturing facility (CDI Laboratories, USA) were exemplary and served to minimise the downtime despite the difficult circumstances.

CDI Laboratories are the contract manufacturer who are producing the PromarkerD kit for the Caribbean launch, having been engaged by Macrotech's sister company Omics Global Solutions, a diagnostics developer based in Puerto Rico.

The production process has included manufacture of specialist reagents, quality control testing, and parallel preparation of clinical documentation, and building of the PromarkerD web portal for remote data analysis.

Production of the antibody reagents required for the in vitro diagnostic (IVD) test kit has been on-going over the last nine months in Australia and Puerto Rico. This process has taken three months longer than originally forecast (ASX: 4 April 2017), however, technical difficulties in this area are common and a 6-12 month timeframe is standard. The antibodies have now been successfully tested for performance, allowing the reagents to be configured into the immunoassay test kit, also known as an ELISA (enzyme linked immunosorbent assay), that can be used in clinical laboratories around the world.

As part of the automatic product registration process, documents will be submitted to the Dominican Republic regulators in December with approvals to be received in January 2018. The product datapack includes submission of the PromarkerD patient report template and instructions for physicians on the interpretation of results. These documents are integral to the global roll out and can be tailored for use in other jurisdictions.

To optimise performance of the test, approvals have been received for the Clinical Protocol to start a replica of the original Australian study in Puerto Rico. Proteomics International will collaborate with Dr Horacio Serrano, Proteomics Lab Director in the Internal Medicine Department, School of Medicine, at the University of Puerto Rico. This data will be used, if required, to adjust the PromarkerD algorithm for regional population variations.

The PromarkerD web-portal for remote submission of test data and generation of the patient test report is undergoing final testing. The portal permits complete protection of the algorithm underpinning PromarkerD and will operate in English and Spanish.

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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 and published in the prestigious journal *Diabetes Care*, 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*.

About Omics Global Solutions and Macrotech Farmacéutica

Omics Global Solutions (OGS) was established to launch innovative products based on the "omics" sciences (proteomics, genomics, etc.) to have an impact on the lives of patients, their caregivers, and medical professionals involved with their treatment. Located in Puerto Rico (USA) it has partnered with Macrotech Farmacéutica to serve the population of the Spanish speaking Caribbean. Macrotech Farmacéutica, established 1995, is a leading health services company and is the exclusive provider of dialysis services, instruments and reagents in the Dominican Republic.

About Proteomics International Laboratories (PILL) (www.proteomicsinternational.com)

Proteomics International is a wholly owned subsidiary and trading name of PILL (ASX: PIQ), a medical technology company focused on proteomics – the industrial scale study of the structure and function of proteins. Proteomics International 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 located on the QEII Medical Campus in Perth, Western Australia. The Company's business model uses its proprietary technology platform across three integrated areas of diagnostics, drug discovery and analytical services.