



Proteomics International

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European PromarkerD patents expanded beyond diabetes

- **Patent protection for Proteomics International's PromarkerD predictive test for diabetic kidney disease expanded to cover prediabetes in Europe**
- **There are currently 537 million adults with diabetes, and an additional 541 million (10.6% of the world's adult population) with prediabetes**
- **Diabetes is the leading cause of chronic kidney disease which affects 100 million Europeans and is estimated to cost the European health system EUR140 billion annually**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) announces that its European patent protection for the Company's PromarkerD predictive test has been expanded to include diagnosing all individuals who are prediabetic and asymptomatic for kidney disease.

Proteomics International's original European patent was restricted to diabetic kidney disease only. The new patent will now provide protection for the use of the PromarkerD test for any individuals with prediabetes, which is an at-risk category for kidney disease.

The International Diabetes Federation estimates there are currently 537 million adults with diabetes, and an additional 541 million (10.6% of the world's adult population) with prediabetes¹. Prediabetes is a term used to describe people with impaired glucose tolerance (IGT) - it indicates a higher risk of developing type 2 diabetes and diabetes-related complications such as kidney disease.

Proteomics International managing director Dr Richard Lipscombe said, *"The expanded patent coverage is an important addition to our PromarkerD intellectual property portfolio and provides an exciting opportunity to increase our addressable market in Europe, where we already have CE Mark registration. There is the potential for the PromarkerD test to be used to determine if a whole new group of people are at risk of developing kidney disease."*

The PromarkerD patent family already covers 63% of the world's diabetics, where the test has been shown to correctly predict up to 86% of otherwise healthy diabetics who go on to develop diabetic kidney disease within four years.

Further clinical studies are needed to demonstrate that PromarkerD can be used to diagnose kidney disease beyond those with diabetes, however, there is already evidence that the biomarkers in the PromarkerD panel are important in chronic kidney disease more broadly².

Chronic Kidney Disease (CKD) is estimated to affect close to 100 million Europeans, with 300 million being at risk, and caused almost 130,000 deaths in Europe in 2019³. Diabetes is the leading cause of kidney failure, accounting for 44% percent of new cases⁴. CKD is estimated to cost Europe EUR140 billion per year, more than the annual healthcare costs for cancer or diabetes⁵.

¹ International Diabetes Federation Diabetes Atlas 10th edition, 2021

² doi.org/10.1038/s41423-018-0088-x; doi: 10.1111/joim.12380

³ Global Burden of Disease Study 2017

⁴ US National Kidney Foundation; www.kidney.org

⁵ European Kidney Healthcare Alliance; www.ekha.eu/the-decade-of-the-kidney/

Proteomics International Laboratories Ltd

ABN 78 169 979 971

Box 3008, Broadway, Nedlands, WA 6009, Australia

T: +61 8 9389 1992 | E: enquiries@proteomicsinternational.com | W: www.proteomicsinternational.com

Chronic kidney disease is often referred to as a ‘silent killer’ because the disease is asymptomatic in its early stages and can go undetected until it is very advanced. In contrast, early detection of the disease allows doctors and patients to take preventative action, which can help remove the need for renal replacement therapies such as dialysis and kidney transplant, potentially saving global healthcare systems billions of dollars a year.

Dr Lipscombe said the new patent complemented and extended the Company's existing broad patent family⁶, including its European patent for 'Diagnosing kidney damage in the early stages' that Proteomics International licensed from the University of Innsbruck in 2016. *“The granting of additional patents like this one further strengthens the Company’s IP position,”* he said.

The European patent has been granted for France, Germany, Italy, Spain, Turkey and the United Kingdom, effective 27 July 2022, and is titled “Biomarkers Associated with Pre-diabetes, Diabetes and Diabetes Related Conditions” (patent number 3343226, and is valid until September 20, 2031).

Authorised by the Board of Proteomics International Laboratories Ltd (ASX:PIQ).

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About PromarkerD (www.PromarkerD.com)

Diabetic kidney disease (DKD) is a serious complication arising from diabetes which if unchecked can lead to dialysis or kidney transplant. PromarkerD is a prognostic test that can predict future kidney function decline in patients with type 2 diabetes and no existing DKD. The patented PromarkerD test system uses a simple blood test to detect a unique ‘fingerprint’ of the early onset of the disease by measuring three serum protein biomarkers, combined with three routinely available conventional clinical variables (age, HDL-cholesterol and estimated glomerular filtration rate (eGFR)). A cloud based algorithm integrates the results into a patient risk report. In clinical studies published in leading journals PromarkerD correctly predicted up to 86% of otherwise healthy diabetics who went on to develop diabetic kidney disease within four years. The PromarkerD test is CE Mark registered in the European Union.

Further information is available through the PromarkerD web portal.

To visit the PromarkerD virtual booth please see: www.PromarkerD.com/product

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. Proteomics International's mission is to improve the quality of lives by the creation and application of innovative tools that enable the improved treatment of disease.

For further information please contact:

Dr Richard Lipscombe
Managing Director
Proteomics International Laboratories Ltd
T: +61 8 9389 1992
E: enquiries@proteomicsinternational.com

Dirk van Dissel
Investor Relations & Corporate Advisor
Candour Advisory
T: +61 408 326 367
E: dirk@candouradvisory.com.au

Kyle Moss
Corporate Advisor
Euroz Hartleys
T: +61 8 9488 1400
E: kmoss@eurozhartleys.com

⁶ PIQ Annual Report 2021