



Proteomics International

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US patent granted for abnormal kidney function drug development using PromarkerD biomarker

- Proteomics International granted US patent for method for identifying drugs for abnormal kidney function
- The patent concerns the use of one of the core PromarkerD biomarkers as a potential novel therapeutic drug target in the treatment of kidney disease
- The patent extends the potential use of the PromarkerD test and Proteomics International could benefit from development of new therapeutics for kidney disease aimed at this biomarker
- This could provide significant commercial value to Proteomics International if a pharma company were to develop a drug treatment using this PromarkerD biomarker
- Kidney disease is one of the leading causes of death in the US with related healthcare spending exceeding \$100 billion annually
- A significant number of global pharma companies are developing drugs for treating kidney disease

Medical technology company Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), which has pioneered the world-leading predictive diagnostic test for diabetic kidney disease, PromarkerD, has been granted a patent in the United States for the use of one of the core PromarkerD biomarkers as a potential drug target.

The US patent number 10191067B2, titled "Method for Identifying an Agent for Treating Abnormal Kidney Function", is valid until 20 September 2031.

In the United States kidney disease is the 9th leading cause of death, and chronic kidney disease due to diabetes is the 16th, in total accounting for 89,000 deaths a year, with related healthcare spending exceeding US\$100 billion annually.

The PromarkerD test measures a panel of protein markers found in the blood, and the new patent is centred on one of these proteins known as CD5 antigen-like (CD5L). CD5L was previously considered to act as a regulator of lipid synthesis, and results published by Proteomics International¹ show CD5L is a diagnostic marker for diabetic kidney disease.

Recent research published by others^{2,3} supports Proteomics International's data and suggests CD5L (also known as 'apoptosis inhibitor of macrophage' or AIM) is involved in a patient's response to acute kidney injury. Consequently, CD5L could be a novel therapeutic target to treat kidney disease, and the new patent covers methods for identifying such drugs. Further research is required to confirm the role played by CD5L and confirm its viability as a drug target.

To avoid patent infringement, any pharma company using a method covered by the claims in the patent in the USA to develop a treatment using CD5L as a target will need to reach commercial agreement with

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Proteomics International. Furthermore, there is the opportunity for the PromarkerD test to be used as a companion diagnostic (CDx) test alongside any therapeutic treatment concerning the CD5L target, both as a pre- and post- treatment diagnostic tool.

Developing new therapeutic treatments for kidney disease has proved a challenge for the pharmaceutical industry. Currently worldwide there are approximately twenty clinical trials in progress to test the performance of drugs for diabetic kidney disease, but to date, no treatments have been approved. Identifying novel therapeutic targets is a key part of the development path.

The patent adds further value to Proteomics International's patent family. Patent protection for the PromarkerD diagnostic test itself has already been granted in the USA (US Patent 9,146,243B2, Method of assessing diabetic nephropathy using CD5 antigen-like [ASX: 27 Oct 2015] and US Patent 9,733,259, Method of Assessing a Subject for Abnormal Kidney Function [ASX: 16 August 2017]), Europe, Australia, Singapore, Russia, China and Japan, with patents pending in other major global jurisdictions.

1. Peters *et al*, Diabetes Care (2017)
2. Oshima *et al*, Clinical Experimental Nephrology (2017)
3. Miyazaki *et al*, Cellular and Molecular Immunology (2018)

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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].

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. The company offsets the cash burn from R&D and product development through provision of specialist analytical services, whilst using its proprietary Promarker™ technology platform to create a pipeline of novel diagnostic tests.

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