



Proteomics International

LABORATORIES LTD

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Update on commercialisation of PromarkerD in the USA

- **Proteomics International has terminated its exclusive licence agreement with Sonic Healthcare USA for the use and commercialisation of the PromarkerD test in the USA**
- **Proteomics International is now free to launch PromarkerD in the US via licensing to alternative pathology laboratories and service providers and/or direct to consumer/ patient (DTC/DTP)**
- **PromarkerD assay established in third party CLIA certified US reference laboratory in preparation for US launch**
- **PromarkerD has been demonstrated in multiple peer-reviewed clinical studies to predict renal decline up to four years in advance in type 2 diabetes, with results now extended to type 1 diabetes**
- **Potential major health impact: addresses a critical health issue for over 32 million people who live with diabetes in the USA**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), a pioneer in predictive diagnostics announces it has terminated its agreement with Sonic Healthcare USA for the use and commercialisation of the PromarkerD predictive test for diabetic kidney disease in the United States of America.

Proteomics International entered into an exclusive licence with Sonic Healthcare USA for the use and commercialisation of PromarkerD in the United States in May last year [ASX: 10 May 2023]. Under the licence agreement there were milestones and key performance indicators required for commercialisation to occur. Certain milestones and key performance indicators have not been met, and Proteomics International has issued a notice of termination under the agreement, which took effect at 5pm AWST on 10 September 2024.

Proteomics International is now free to licence PromarkerD to other parties in the USA. Proteomics International is targeting a US launch of PromarkerD in FY25 using two Go-to-Market strategies, namely licensing to alternative pathology laboratories and service providers and direct to consumer/patient (DTC/DTP) (PIQ June Quarterly; [ASX: 30 July]). The PromarkerD assay was recently established in the USA in a third party CLIA certified reference laboratory as an avenue to demonstrate further clinical applications of PromarkerD, and this laboratory can also be used to implement the Go-to-Market strategies. The Company is also in discussions with appropriate service providers/partners to enable commercial sales.

The performance of PromarkerD has previously been demonstrated in multiple peer-reviewed clinical studies to accurately predict the onset of diabetic kidney disease and future kidney function decline up to four years in advance in patients with type 2 diabetes. These findings were recently extended to predicting renal decline in type 1 diabetes [ASX: 23 August]. This breakthrough followed extensive sample analysis using the PromarkerD immunoassay on a high-throughput robotic platform in Proteomics International's ISO 17025 and ISO 13485 certified Perth laboratories [ASX: 30 July].

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 1 or type 2 diabetes and no existing DKD. The patented PromarkerD test system uses a novel 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.

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