



Proteomics International

LABORATORIES LTD

ASX Release

2 June 2022

ASX code: PIQ

PromarkerD registration submitted to the TGA

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) is pleased to announce it has filed a submission to the Australian Therapeutic Goods Administration (TGA) for inclusion of PromarkerD - the world's first predictive test for diabetic kidney disease - in the Australian Register of Therapeutic Goods (ARTG).

PromarkerD has been shown in extensive clinical studies to predict the onset of diabetic kidney disease up to four years before clinical symptoms appear.

Proteomics International Managing Director Dr Richard Lipscombe said this was an important step for the national and global roll-out of PromarkerD because Australia is one of the major reference countries in addition to the US Food & Drug Administration (FDA), European Union CE Mark, Health Canada and Japan. *"Home country approval will also enable product registration to proceed in multiple other countries, for example South-East Asia and the Middle East, where we see substantial market opportunities"*, he said. The PromarkerD test is already CE Mark registered in the European Union.

The submission is following an "abridged" registration path [ASX: 28 April], and builds upon the specialised ISO 13485 Quality Control and Quality Assurance certification of Proteomics International and its manufacturing partners [ASX: 12 August 2021]. The TGA will now review the submission, a process which is expected to take six to nine months, and if approval for registration is successful then PromarkerD can be sold in Australia.

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

ENDS

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

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

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

For personal use only