ASX Release
28 February 2025

ASX code: PIQ

Proteomics International opens CLIA certified reference laboratory in the USA to provide suite of precision diagnostic tests

- **Proteomics International opens its Proteomics International USA Reference Laboratory in Irvine, California, USA**
- **Laboratory secures California State licence and Clinical Laboratory Improvement Amendment (CLIA) certificate as a certified clinical laboratory**
- **Certification enables the PromarkerD predictive blood test for diabetes-related chronic kidney disease (DKD) to be offered in the USA, with precision diagnostic tests PromarkerEso for esophageal cancer and PromarkerEndo for endometriosis to follow**
- **PromarkerD has been shown in multiple peer-reviewed studies to predict the onset of chronic kidney disease up to four years in advance in type 2 and type 1 diabetes**
- **Health impact: addresses a critical health issue for 32 million adults in the USA who have diabetes, with DKD costing $130 billion per year in the USA**

Proteomics International Laboratories Ltd (Proteomics International; the Company; ASX: PIQ), a pioneer in precision diagnostics, is proud to announce that it has opened its US Reference Laboratory and been awarded a Clinical Laboratory Improvement Amendment ("CLIA") certificate of registration, as a certified clinical laboratory.

The Proteomics International USA laboratory is located in the healthcare precinct of Irvine, California, and has also received a California State Licence. With the certification, Proteomics International can offer its clinical laboratory services within the United States in all jurisdictions that recognise CLIA accreditation[1].

The CLIA-certified laboratory will initially offer Proteomics International's validated PromarkerD test for predicting the onset of diabetes-related chronic kidney disease (DKD) in type 2 diabetes patients. The laboratory also has scope in future to offer other tests from the Company's suite of precision diagnostics, including PromarkerEso for esophageal cancer and PromarkerEndo for endometriosis.

Proteomics International Managing Director Dr Richard Lipscombe said the laboratory certification was an enabling milestone in the commercialisation of the Company's suite of precision diagnostic tests. *"This achievement is testament to the technical expertise and drive of our team to bring our potentially life-changing tests to patients in the US. We see enormous market potential immediately for PromarkerD, and subsequently PromarkerEso and PromarkerEndo, to improve patient lives and save the US healthcare system millions of dollars."*

Diabetes affects over 32 million adults in the US and 537 million people worldwide, and chronic kidney disease is a major complication, leading to severe health outcomes and increased mortality[2]. Diabetes has

[1] CLIA certification is recognised nationwide, except for Maryland, Pennsylvania, Rhode Island, New York, and Washington DC

[2] International Diabetes Federation 2021

emerged as the largest single cause of end-stage renal disease (leading to dialysis or kidney transplant), and DKD costs $130 billion per year in the USA[3].

The Irvine, CA, laboratory mirrors Proteomics International's existing Perth laboratory and has been established and will operate within pre-stated Company budgets. Importantly, the laboratory has ability to be scaled as necessary, and new tests and instrumentation can be added simply when required. This provides the Company with a cost-effective way of introducing its specialised diagnostic tests to the major market of the USA.

The validated PromarkerD blood test for predicting diabetes-related chronic kidney disease is scheduled to launch in the US in Q2 CY25. The test will initially be available through a direct-to-consumer/patient (DTC/DTP) go-to-market route as a prelude to out-licensing to major industry players in the diagnostics sector.

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

ENDS

About CLIA

CLIA is the US federal program administered by the US Centres of Medicare & Medicaid Services (CMS) to govern the quality and accuracy of clinical testing in the US. The Clinical Laboratory Improvement Amendments act of 1988 (42 USC 263a) and the associated regulations (42 CFR 493) provides the authority for certification and oversight of clinical laboratories and laboratory testing. CLIA-designated laboratories are authorised to offer clinical testing in the US, particularly laboratory developed tests (LDTs).

About PromarkerD (www.PromarkerD.com)

Diabetes-related chronic 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 blood test to detect a unique 'fingerprint' of the early onset of the disease. The multivariate test measures a select panel of protein and clinical biomarkers, before 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.

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 precision 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
Candour Advisory
T: +61 408 326 367
E: dirk@candouradvisory.com.au

[3] US Renal Data System 2020