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# Proteomics International launches PromarkerD into the US at the 85<sup>th</sup> Scientific Sessions of the American Diabetes Association

- PromarkerD is a blood test validated for predicting diabetes-related chronic kidney disease (DKD) up to four years before symptoms appear
- PromarkerD launched today in the US at the annual American Diabetes Association Scientific Sessions in Chicago, Illinois, the largest gathering of diabetes professionals in the world
- The test will initially be available in California and provided by Proteomics International's recently opened Clinical Laboratory Improvement Amendment (CLIA) certified Reference Laboratory
- Major health impact: Potential to improve outcomes for over 32 million adults in the US with diabetes and at risk of DKD by enabling earlier intervention, improving care and reducing healthcare costs for DKD which exceed \$130 billion annually

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), a pioneer in precision diagnostics, proudly announces the initial US launch of its groundbreaking predictive test for diabetic kidney disease, PromarkerD, at the 85<sup>th</sup> Scientific Sessions of the American Diabetes Association (ADA) in Chicago, Illinois.

PromarkerD is a laboratory-based blood test that can predict the onset of diabetes-related chronic kidney disease (DKD) up to four years in advance in people with type 2 diabetes. Validated in multiple large-scale studies, this innovative test empowers clinicians and patients by enabling early intervention to slow or prevent kidney function decline, an urgent need given that 1 in 2 adults with diabetes currently develop kidney disease<sup>1</sup>.

The ADA's Scientific Sessions, running June 20-23, 2025, represent the largest gathering of diabetes professionals in the world, making it an ideal platform to unveil PromarkerD to the US market. Proteomics International will engage with healthcare providers, opinion leaders, patient advocacy groups and channel partners to showcase the test's utility through real-world case studies. The Company will also present key clinical data as a Late Breaking Abstract, a program for the inclusion of noteworthy and timely research advances, titled "Next-Generation PromarkerD vs Standard of Care for Assessing Kidney Function Decline in Type 2 Diabetes".

Proteomics International Managing Director Dr Richard Lipscombe said, "We're excited to introduce PromarkerD to the US at such a prestigious event. This marks a significant milestone in our global commercialisation strategy and underscores our commitment to addressing the diabetes epidemic through precision medicine."

Renowned diabetes care and nurse practitioner Davida Kruger, of Henry Ford Health in Detroit, added, "PromarkerD represents a paradigm shift in diabetes care. Early identification of patients at risk for kidney disease allows clinicians to implement preventative strategies long before irreversible damage occurs. This is the kind of innovation that transforms patient lives."

<sup>&</sup>lt;sup>1</sup> Nat Reviews Disease Primers (2015); doi: 10.1038/nrdp.2015.18

The introduction of PromarkerD to the US signals a major commercial opportunity with the US representing the largest global healthcare market, and home to over 32 million people with diabetes<sup>2</sup>. PromarkerD is being offered to US patients and primary care physicians through the Company's fully integrated digital solution for direct-to-consumer engagement, first instituted in Australia.

The test will initially be available in California and provided by Proteomics International's recently opened Clinical Laboratory Improvement Amendment (CLIA) certified Reference Laboratory located in Irvine, California [ASX: 28 February], and supports plans for the broader US roll-out.

The market availability of PromarkerD in the US is a fundamental step in the Company's hybrid commercialisation strategy of utilising direct to consumer (DTC) and partner sales avenues. This real-world use will facilitate the progression of discussions with potential license and distribution partners and the health insurance industry.

According to the American Society of Nephrology many patients suffer silently at first because chronic kidney disease is largely asymptomatic at the beginning. This lack of early detection can be fatal, as kidney dysfunction lasting longer than three months is often irreparable<sup>3</sup>.

DKD currently costs the US healthcare system US\$130 billion annually<sup>4</sup>, which is equivalent to over a quarter of the US Medicare total annual budget. Without effective intervention, projections indicate over one million US kidney failure patients by 2030, representing an increasingly unsustainable fiscal burden on taxpayers and the American workforce<sup>5</sup>.

#### **Commercial Pathway in Australia**

Proteomics International launched PromarkerD in Australia on World Kidney Day [ASX: 13 March] through a clinician driven strategy supported by an on-line patient awareness campaign. This pilot program is focussed on Western Australia and the Northern Territory, and has enabled the Company to refine its direct-to-consumer platform and logistics processes.

Blood samples are analysed at Proteomics International's Australian laboratory using its proven technology platform. The method employed for this test is pending accreditation by the National Association of Testing Authorities (NATA) and has been conducted in line with ISO 15189 laboratory standards for clinical testing, adhering to NATA-accredited methodologies. Once final certification is received the test will be made available nationwide.

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

**ENDS** 

## 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. Country specific use of this product is subject to the relevant regulatory approvals.

Proteomics International recommends that patients concerned about DKD seek advice from their doctors.

Further information on DKD is available through the www.mytest.health web portal.

<sup>&</sup>lt;sup>2</sup> International Diabetes Federation 2021

<sup>&</sup>lt;sup>3</sup> www.asn-online.org/nationalkidneymonth/

<sup>&</sup>lt;sup>4</sup> US Renal Data System 2020

 $<sup>^5 \</sup> www.kidney.org/sites/default/files/2025-04/2025-04-28\_letter-to-omb\_fy2026-budget\_final.pdf?utm\_source$ 

#### 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.

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