



ASX/Media Release

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## **US Patent granted for Predictive and Diagnostic Test for Diabetic Kidney Disease**

- **Grant of US patent is a critical milestone in the development of the Diagnostic Test for Diabetic Kidney Disease in the world's largest health care market**
- **Patent provides protection as both a predictive and diagnostic test in the USA**
- **Ability to accurately detect early onset of Diabetic Kidney Disease via a simple blood test has the potential to save health care systems globally \$100s of millions annually**

Life sciences company Proteomics International Laboratories Ltd (ASX: PIQ) (the Company, PILL) is pleased to announce it has been granted a US patent for its PromarkerD Diagnostic Test for the early diagnosis of diabetic kidney disease (DKD).

The patent provides protection for the use of PromarkerD as both a predictive (prognostic) and diagnostic test in the USA, and is valid until 20 September 2031. The patent is entitled, "Method of assessing diabetic nephropathy using CD5 antigen-like" (patent number: US 9,146,243 B2).

The grant of patent represents a critical milestone in the development and commercialisation pathway for PILL's Diagnostic Test in the USA – the world's largest health care market.

The grant of this patent is particularly significant, as there is an increasing level of stringency being applied to diagnostic patent applications. The Australian High Court has determined that DNA sequences can no longer be patented, which follows an earlier finding by US Federal Courts. PILL's Managing Director, Dr Richard Lipscombe commented: *"We are delighted to have this protein based patent granted in the USA in such a challenging diagnostic patent environment."*

The patent contains the essential core claims within International Patent Application PCT/AU2011/001212 "Biomarkers associated with pre-diabetes, diabetes and diabetes related conditions" – namely designating a patient as having an increased risk of developing diabetic kidney disease by measuring a panel of protein biomarkers.

PILL's patented test was developed from the Company's world-leading proprietary proteomics-based technology platform. It uses protein biomarkers found in the blood to provide an early and accurate detection of the presence of disease.

### **Australian patent also granted**

The Company is pleased to confirm that its Australian patent for PromarkerD, entitled "Biomarkers associated with pre-diabetes, diabetes and diabetes related conditions" (Australian Patent Application 2011305050) granted on the 3<sup>rd</sup> September. This patent is also valid until September 2031.

PILL is also seeking patent protection for PromarkerD in other major global markets including Europe, China and India, and will advise further on these in due course.

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## Market Opportunity

The potential commercial and medical benefits, as well as cost savings, from PILL's diagnostic test are huge. Diabetes is the world's fastest growing medical problem. Globally it is estimated that 387 million people have diabetes and this is expected to grow by 200 million in the next 20 years (International Diabetes Federation). Kidney disease is one of the major complications of diabetes, and in the USA 35% of adults with diabetes have chronic kidney disease and 20% will progress to kidney failure (US Centre for Disease Control).

The application of PromarkerD has the potential to identify the tens of millions of people at risk of significant and rapid decline in kidney function. This represents a massive market opportunity for the technology owner/developer and any licensing partner(s).

The ability to accurately detect the early onset of DKD via a simple blood test and then prescribe appropriate treatment to prevent the condition progressing to dialysis or kidney transplant could save health care systems globally \$100s of millions annually.

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### About Proteomics International Laboratories

PILL is an ASX listed (ASX: PIQ) life science company focused on the area of proteomics – the industrial scale study of the structure and function of proteins. Proteomics is an integral part of the biotechnology and life sciences industries and plays a key role in understanding disease and biological systems.

PILL is recognised as a global leader in its field. It received the world's first ISO 17025 laboratory accreditation for proteomics services, and operates from state-of-the art facilities at the Harry Perkins Institute of Medical Research in Perth, Western Australia. The Company's business model uses its proprietary technology platform which operates across three synergistic proteomics-based business units in massive growth markets:

- 1. Diagnostics:** Biomarkers of diseases and personalised medicine - focus on diabetic kidney disease and Alzheimer's disease. The biomarkers market is estimated to double in size to \$45.6 billion by 2020.
- 2. Analytical services:** Specialist contract research, analytical testing and consultancy - fee for service model. The specialist proteomics market alone represents a massive global market estimated to be worth \$20.8 billion by 2018.
- 3. Drug discovery:** Therapeutic drug discovery with a focus on painkillers and antibiotics. The peptide therapeutics market is currently estimated to be worth \$17 billion.

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