



Proteomics International

LABORATORIES LTD

**ASX release
9 August 2022**

ASX code: PIQ

Proteomics International signs binding letter of intent with Sonic Healthcare USA to take PromarkerD into the US market

- **Proteomics International and Sonic Healthcare USA sign binding and exclusive Letter of Intent regarding an exclusive licence for PromarkerD in the United States**
- **Estimated 32 million people or eleven per cent of the American population live with diabetes - testing these patients with PromarkerD could help identify their risk of developing diabetic kidney disease**

Proteomics International Laboratories Ltd (Proteomics International; the Company; ASX: PIQ) is pleased to announce it has signed a binding and exclusive letter of intent (LOI) with Sonic Healthcare USA, Inc. (a division of Sonic Healthcare Limited; ASX: SHL) (Sonic Healthcare USA) regarding entering into an exclusive licence for use of the Company's PromarkerD test for diabetic kidney disease in the United States.

PromarkerD is a newly developed blood test that can predict kidney function decline in type 2 diabetes. Diabetic kidney disease (DKD) is a major complication arising from diabetes, and PromarkerD is the only available test capable of predicting the onset of the disease in patients with diabetes and no existing DKD [ASX: 5 November 2021].

The binding and exclusive LOI documents the preliminary terms and expectations for how Proteomics International and Sonic Healthcare USA will work together to bring the PromarkerD test to patients in the US (excluding Puerto Rico), and for finalising an Exclusive Licence Agreement by 31 December 2022 (which may be extended), subject to the parties formalising milestone events and timelines in relation to the commercialisation process.

Key milestones under the LOI include optimising the test for a high-throughput environment within Sonic Reference Laboratories to enable commercial sale of PromarkerD, preparing for a submission to secure a Proprietary Laboratory Analysis (PLA) reimbursement code for the PromarkerD test [ASX: 28 October 2021], and forecasting sales targets for PromarkerD in the US marketplace. The Company anticipates each of these milestones to be completed within the next 2-5 months.

The LOI also provides industry-standard terms for payment for PromarkerD test reagents and describes the royalty terms on commercial sales of the test. The LOI is also subject to standard terms and conditions (including confidentiality) and warranties typical for a document of its type.

Proteomics International Managing Director Dr Richard Lipscombe said this was a pivotal point in the global roll-out of PromarkerD. *"The US is the world's premier healthcare market and we are delighted to be working with Sonic Healthcare USA, one of the world's leading diagnostic companies. It is rewarding for us to see their appreciation for what PromarkerD can offer diabetes patients. We have been working with Sonic Healthcare USA towards this goal for fifteen months, and now look forward to building upon this foundation and taking our world first predictive test for diabetic kidney disease into not only the US, but also Europe where the test already has regulatory approval."*

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Key Opinion Leader Professor David Klonoff, MD, clinical professor of medicine at the University of California at San Francisco, and an endocrinologist specialising in bioengineered solutions for people with diabetes, said he was looking forward to the commercialisation of the PromarkerD assay in the United States.

“It is a significant step forward to bring this product to the US market now since PromarkerD represents an effective laboratory tool that will enable clinicians to provide precision medicine diagnosis and prognosis for patients with type 2 diabetes who are at risk of renal failure.”

In the USA an estimated 32 million people, or 11 per cent of the population, live with type 2 diabetes¹. According to the US Renal Data System, the total cost of diabetic kidney disease is USD 130 billion per year in the USA alone².

The early diagnosis of DKD using PromarkerD testing in diabetes can help inform doctors' treatment decisions to improve clinical outcomes for patients [ASX: 2 August 2022], and could drive improved therapeutic interventions [ASX 16 July and 11 August 2021]. Reducing or delaying the progression of DKD and consequently the incidence of dialysis and kidney transplant would result in significant cost savings for health care systems [ASX: 2 July 2021].

US Laboratory Developed Test (LDT) & Proprietary Laboratory Analyses (PLA) Reimbursement Code

The PromarkerD test will be launched in the US via the LDT pathway using Sonic Healthcare USA's CLIA certified clinical laboratories. The Company will also seek a unique code for PromarkerD once the test is available in the US. New reimbursement codes are approved quarterly by the American Medical Association (AMA) and its Current Procedural Terminology (CPT) Editorial Panel, and follow assessment of the economic health benefit and clinical utility of a new test. A CPT Proprietary Laboratory Analyses (PLA) code uniquely identifies a test for the laboratory and the payors.

As for any novel test, market penetration cannot be reliably predicted, hence for the new market it is not possible to quantify the potential financial impact on Proteomics International in any given timeframe.

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

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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.

About Sonic Healthcare USA (www.sonichealthcareusa.com)

Sonic Healthcare USA is a subsidiary of Sonic Healthcare Limited (ASX:SHL), one of the world's largest medical diagnostic companies, providing laboratory services to medical practitioners, hospitals and community health services, with operations in seven countries, on three continents and providing care to over 100 million patients each year. Sonic Healthcare USA is a leading provider of state-of-the-art laboratory and pathology services throughout the USA with eight operating divisions and over eight thousand US based employees. Sonic Healthcare USA utilizes a federated business model that emphasizes medical leadership and community based testing services to provide outstanding quality and service to doctors and the patients that they serve.

¹ International Diabetes Federation Diabetes Atlas 10th edition, 2021

² US Renal Data System 2020

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

For further information please contact:

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