



Proteomics International

LABORATORIES LTD

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Clinical Advisory Board expanded to support PromarkerD USA and global rollout

- **Proteomics International appoints additional key opinion leaders (KOLs) to its world class PromarkerD Clinical Advisory Board**
- **New advisory board members comprise highly respected healthcare professionals specialising in primary care diabetes education and management in the United States**
- **Clinical Advisory Board able to provide tailored advice from the 'voice of the customer' (patients and clinicians) perspective on the rollout of the PromarkerD predictive test for diabetic kidney disease for type 2 diabetes patients**
- **Sonic Healthcare USA and Proteomics International continue to work closely together with strong progress being made towards reimbursement for the PromarkerD test**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) is pleased to announce it has appointed additional members to its Clinical Advisory Board adding world leading healthcare professionals from the United States specialising in diabetes care and education. The expanded Clinical Advisory Board will provide valuable insights and guidance to the Company and its laboratory and distribution partners on the clinical and commercial strategies for the PromarkerD rollout in the US and global markets.

PromarkerD is a newly developed blood test that can predict diabetic kidney disease before clinical symptoms appear, and can help doctors make treatment decisions and improve outcomes for patients with type 2 diabetes.

Diabetes care and education involves a broad range of healthcare professionals from different specialities including general practitioners, endocrinologists, nephrologists, pharmacists, nurses, diabetes educators and dietitians. The new Clinical Advisory Board members bring extensive experience and knowledge of diabetes care and will provide valuable insights and guidance from the 'voice of the customer' (patients and clinicians) perspective to help successfully launch PromarkerD in the US and globally.

Dauida Kruger, a Nurse Practitioner and Director of Clinical Research in the Division of Endocrinology, Diabetes Bone and Mineral Disorders, Henry Ford Health and one of the new appointees commented that the detection and treatment of diabetes involves a broad range of healthcare professionals from a multitude of specialities.

"Together we are in a good position to help usher in new technologies such as PromarkerD to help advance the treatment and care of patients with diabetes and potentially slow the progression of diabetic kidney disease," she said.

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Proteomics International Managing Director Dr Richard Lipscombe said it was exciting to have such a prestigious group of diabetes experts wanting to join the PromarkerD Clinical Advisory Board. *“The new members bring a wealth of knowledge in treating diabetes patients and they will be important advocates for the use of the PromarkerD test. We look forward to working with them as we bring PromarkerD to patients across the United States.”*

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

Update on the PromarkerD US rollout and PLA reimbursement code

Proteomics International continues to work closely with its intended licence partner Sonic Healthcare USA towards the formal launch of PromarkerD in the USA [ASX: 1 March 2023]. Both parties continue to commit substantial resources to this process and to finalising the licence agreement. Of particular note, strong progress is being made towards reimbursement for the test.

The new dedicated CPT Proprietary Laboratory Analyses (PLA) code for PromarkerD (0385U) was granted to Sonic Reference Laboratory as the clinical laboratory and Proteomics International as the manufacturer [ASX 3rd January 2023], and became effective from 1st April 2023, which means service providers (laboratories) may now begin to report the PromarkerD test using the code.

A critical part of the rollout of PromarkerD is engagement with payers which is ongoing, with the Centers for Medicare & Medicaid Services (CMS) recently listing the code in its CY24 Clinical Laboratory Fee Schedule (CLFS) Annual Laboratory Meeting Code List. This is an essential step towards establishing a payment rate for PromarkerD.

To support the uptake of PromarkerD testing and the ongoing engagement with KOLs, industry representatives and the diabetes community, Proteomics International will also attend the American Diabetes Association’s (ADA) 83rd Scientific Sessions in San Diego, June 23-26, 2023, and the Endocrine Society 2023 Annual Meeting, Chicago, June 15-18, 2023. The latter is the top global meeting for endocrinology research and clinical care attracting over 7,000 delegates, whilst the ADA Scientific Sessions is one of the world’s largest diabetes conferences, with pre-pandemic attendance of over 15,000 professional attendees from 115 countries.

Clinical Advisory Board

The new primary care clinical advisors are from top hospitals and medical universities in the United States and will join the existing preeminent PromarkerD Clinical Advisory Board members consisting of endocrinology and nephrology KOLs [ASX: 22 April 2022]. The new members are:

David Kruger MSN,APN-BC,BC-ADM (USA)

Ms Kruger has been a certified nurse practitioner in diabetes for more than 40 years at Henry Ford Health in Detroit, Michigan, USA. Her role includes both clinical practice and research. She is board certified by the American Nurses Association Credentialing Center in Primary Care and by the American Association of Diabetes Educators in Advanced Diabetes Management. Ms Kruger is the past Chair of the American Diabetes Association's (ADA) Research Foundation and has served on the ADA's Research Policy Committee. She is also a past President of Health Care and Education for the ADA. She served as editor of Diabetes Spectrum from 2005-2008 and as the Editor in Chief of Clinical Diabetes from 2011-2016.

Ms Kruger has been a principal investigator on numerous research projects and has written widely on diabetes care. Her awards include the Florence Nightingale award for excellence in research, the ADA Rachmeil Levine Award for Distinguished Service, the ADA Award for Outstanding Service in Diabetes

¹ International Diabetes Federation Diabetes Atlas 10th edition, 2021

² US Renal Data System 2020

Research Funding, The ADA Wendell May's Award, The 2014 Clara Ford Award for Nursing Excellence in Research and Education, Wayne State University School of Nursing 2014 Alumna of the Year, the 2017 International Diabetes Center Donnell Etwiler Memorial Award, and the ADA 2017 Outstanding Educator in Diabetes Award.

Joshua Neumiller PharmD, CDCES, FADCES, FASCP (USA)

Dr Josh Neumiller is a professor of pharmacotherapy at Washington State University and a clinical researcher at Providence Medical Research Center, USA. He has authored over 100 articles and book chapters related to management of diabetes and diabetes-related complications. Dr Neumiller has served in numerous service roles for the ADA and other professional organisations, including as Chairperson for the ADA Professional Practice Committee from 2018-2019 whose primary responsibility was revising the ADA Standards of Medical Care in Diabetes each year.

Dr Neumiller was awarded the 2016 Albert B. Prescott Pharmacy Leadership Award and named the 2021 ADCES Diabetes Care & Education Specialist of the Year for his work in diabetes care, research and education.

Neil Skolnik MD (USA)

Dr Neil Skolnik is a Professor of Family and Community Medicine at the Sidney Kimmel Medical College of Thomas Jefferson University and Associate Director of the Family Medicine Residency Program at Jefferson Health - Abington. He is an academic family physician who sees patients and teaches residents and medical students in the family medicine residency program at Jefferson Health - Abington in Pennsylvania, USA. Dr Skolnik has written and edited five books and published more than 400 articles in both medical journals as well as the lay literature, including USA Today.

Dr Skolnik lectures nationally on a range of topics, with a special interest in diabetes, asthma, COPD, exercise in medicine, coronary disease risk factor management, and the medical humanities. He has served on the Diabetes Covid-19 core leadership team for the ADA. Dr Skolnik also hosts and produces "Diabetes Core Update," the ADA's official monthly podcast reviewing the most important new articles to come out in the diabetes literature every month.

Hope Warshaw MMSc, RD, CDCES, BC-ADM, FADCES (USA)

Ms Warshaw is a registered dietitian (RD) and a certified diabetes care and education specialist (CDCES) with more than 40 years of expertise in diabetes care and education. She holds a board certification in advanced diabetes management (BC-ADM), is a consultant to several diabetes and nutrition-focused corporations.

Ms. Warshaw has authored numerous professional publications in the focus of diabetes and nutrition and has written several consumer books for the ADA. More recently, she has and continues to write articles for online diabetes information resources, including regular contributions to diaTribe Learn. Ms Warshaw has also held positions locally and nationally for The Academy of Nutrition and Dietetics, the ADA and the Association of Diabetes Care and Education Specialists (ADCES). She served as President of the ADCES during 2016 and has served as Chair of the Academy's Foundation during 2022-2023.

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

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About PromarkerD (www.PromarkerD.com)

Diabetic kidney disease (DKD) is a serious complication arising from diabetes which if unchecked can

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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 available in the USA as a Laboratory Developed Test (LDT), is pending approval from the TGA in Australia, and 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

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.

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