Media / ASX Release

ASX code: PIQ

World-first predictive test for Diabetic Kidney Disease could save $384 billion over 10 years

- **Independent modelling estimates the PromarkerD predictive test for diabetic kidney disease (DKD) would increase the quality of care and could save US payers almost USD400 billion over 10 years**
- **The US is home to 31 million adults with diabetes who are at risk of DKD - cost savings stem from slowed disease progression, delayed or prevented dialysis and kidney transplants, and fewer dialysis crashes**
- **Results to be presented at the American Diabetes Association's 81st Scientific Sessions, 25-29 June 2021**

25 June 2021, Boston, USA and Perth, Australia: Proteomics International Laboratories Ltd (ASX: PIQ) announces testing for diabetic kidney disease with the PromarkerD prognostic blood test could save US payers almost USD400 billion over 10 years, research suggests. The ground-breaking PromarkerD test is the only test capable of predicting the onset of diabetic kidney disease in patients with type 2 diabetes.

Independent consultant Boston Healthcare Associates modelled the budget impact of using PromarkerD compared to the current standard of care, to proactively test for diabetic kidney disease in patients with type 2 diabetes but who otherwise have no sign of kidney disease.

It found the test—developed by Proteomics International—could result in net savings to Medicare and commercial insurers of USD384 billion over 10 years.

There are 31 million adults with diabetes in the US. Instigating the simple test, set at USD150 for an annual testing regime, would cost $8.9 billion annually, however, could produce savings of USD473 billion over ten years. Savings stem primarily from slowing the progression of diabetic kidney disease, followed by benefits from delaying or preventing dialysis and kidney transplants, and a reduction in dialysis crashes.

The findings will be presented at the virtual American Diabetes Association's 81st Scientific Sessions at 11:30am ET on Friday 25 June 2021 *(presentation details below).*

Proteomics International managing director Dr Richard Lipscombe said the research extends the initial modelling [ASX: 13 May] to emphasise the benefits of an early, accurate and cost-effective prognosis. "*Testing patients with type 2 diabetes every 6-12 months with PromarkerD would enable early intervention for those at high-risk of developing diabetic kidney disease*," he says.

"*This would decrease the need for expensive late-stage interventions, such as dialysis and kidney transplants. It would also assist in stratifying which patients would receive new DKD preventative therapeutic treatments. The potential benefits to the patient and the healthcare system are enormous.*"

The PromarkerD test has received CE Mark registration and is currently available in Europe, with Proteomics International in advanced discussions to bring the test to the clinic in the US.

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

ENDS

About PromarkerD (www.PromarkerD.com)
PromarkerD is a predictive test for the early detection of chronic kidney disease (CKD) in patients with type-2 diabetes. CKD is one of the major complications arising from diabetes and if unchecked can lead to dialysis or kidney transplant.

The patented PromarkerD test system uses a simple blood test to detect a unique 'fingerprint' of the early onset of disease by measuring three serum protein biomarkers, combined with three routinely available conventional clinical variables (age, HDL-cholesterol and estimated glomerular filtration rate (eGFR)).

In clinical studies published in leading journals PromarkerD correctly predicted 86% of otherwise healthy diabetics who went on to develop chronic kidney disease within four years. The PromarkerD immunoassay, the PromarkerD mass spectrometry assay, and the PromarkerD software hub have each achieved CE Mark registration in the European Union.

Further information is available through the PromarkerD web portal.

ADA 81st Scientific Sessions poster presentation (#813-P; 13-A Health Care Delivery - Economics), titled: *Demonstrating the Economic Health Benefit of using the PromarkerD In Vitro Diagnostic Test in the Prediction of Diabetic Kidney Disease*
Burchenal W[1], Datar M[1], Peters KE[2], Fernandez GC[2], Morrison JC[2], Lipscombe RJ[2]
[1]Boston Healthcare Associates, Boston, MA, USA, [2]Proteomics International, Perth, WA, Australia

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. It received the world's first ISO 17025 laboratory accreditation for proteomics services, and operates from state-of-the-art facilities located on Perth's QEII Medical Campus.

Proteomics International's business model is centred on the commercialisation of the Company's world-leading test for diabetic kidney disease, PromarkerD. The Company offsets the cash burn from R&D and product development through provision of specialist analytical services, whilst using its proprietary Promarker™ technology platform to create a pipeline of novel diagnostic tests.

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ASX Release
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Update on study presented at ADA Conference

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) refers to its ASX release of 25 June 2021 titled "Modelling shows PromarkerD could save US payers $384 billion" ("Announcement").

The purpose of the Announcement was to report the findings of the economic health benefit study due to be presented at the 81st Scientific Sessions conference of the American Diabetes Association. The Announcement was made to ensure compliance with the Company's continuous disclosure obligations.

Following consultation with ASX, and to ensure the findings from the study are not interpreted as forecast financial information under ASIC Regulatory Guide 170, Proteomics International has agreed to retract that Announcement. In retracting that Announcement, Proteomics International notes that investors should not rely on the information as a basis for making an investment decision about its shares. Importantly, shares in Proteomics International have not traded since release of the Announcement.

The economic health benefit study was undertaken to support the Company's application for a unique reimbursement code for PromarkerD in the US, and was conducted by independent consultant, Boston Healthcare Associates.

Proteomics International is pursuing a CPT Proprietary Laboratory Analyses (PLA) code, which will uniquely identify the PromarkerD test for laboratories and payors in the US. Reimbursement codes and payer coverage in the US are initiated through the American Medical Association (AMA) and its Current Procedural Terminology (CPT) Editorial Panel.

Formal economic health modelling is an essential component of achieving a unique reimbursement code for PromarkerD in the US, and ensuring subsequent reimbursement of the cost of the test by insurance companies and other payors. All companies seeking reimbursement for any new test are required to provide a dossier demonstrating the potential economic health benefit of the test.

The second element to achieving reimbursement is demonstrating the clinical utility of PromarkerD, namely the impact of PromarkerD on patient treatment decisions by primary care physicians and specialist endocrinologists. A clinical utility study has been conducted by Boston Healthcare Associates and is currently subject to peer review prior to publication.

Boston Healthcare Associates are engaged on a fee-for-service basis to conduct the economic and clinical utility studies required to support the Company's application for a unique reimbursement code for PromarkerD in the US. Boston Healthcare Associates is a global firm with expertise in pricing, reimbursement, market analysis and health economics to support healthcare clients in product development, commercial launch, business development and portfolio management.

The economic health benefit study was presented at the world's leading diabetes conference, the 81st Scientific Sessions of the American Diabetes Association (ADA), held from 25 to 29 June 2021.

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

ENDS

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The following poster was presented at the American Diabetes Association's 81st Scientific Sessions (ADA) from June 25–29, 2021

Demonstrating the Economic Health Benefit of using the PromarkerD In Vitro Diagnostic Test in the Prediction of Diabetic Kidney Disease

Email: info@promarkerd.com
Websites: www.promarkerd.com, www.proteomics.com.au

Burchenal W[1], Datar M[1], Peters KE[2], Fernandez GC[2], Morrison JC[2], Lipscombe RJ[2]
[1]Boston Healthcare Associates, Boston, MA, USA, [2]Proteomics International, Perth, WA, Australia

Presented at the Virtual ADA 81st Scientific Sessions
13-A Health Care Delivery – Economics
Poster 813-P

Background

- Diabetic kidney disease (DKD) develops in 1 in 3 people with type 2 diabetes (T2D) and is the leading cause of end-stage renal disease (ESRD).[1]
- Most people with CKD (~90%) are unaware they have the disease,[1] with early detection and treatment essential to prevent further kidney injury.[2]
- DKD costs the US Medicare system $50 billion annually.[3]
- PromarkerD is an innovative biomarker-based blood test that can predict future renal function decline in the next 4 years in people with T2D who have no or mild existing DKD (eGFR >30 mL/min/1.73m^2).
- PromarkerD predicts incident DKD (reduction in eGFR to <60 mL/min/1.73m^2) or eGFR decline ≥30% in people with baseline eGFR <60 mL/min/1.73m^2.
- PromarkerD test scores are categorized as low-, moderate- or high-risk to optimize DKD management.

Aim

- To develop a budget impact model to estimate the net savings to US payers over a 10-year time horizon from covering the PromarkerD test versus current standard-of-care (SOC) without PromarkerD.

Methods

- The total number of people with T2D and no/mild DKD (KDIGO categories G1-3b)[4] in the US (~31 million)[5] were included in the budget impact model (Figure 1).
- The budget impact model evaluated potential savings to US payers from covering the PromarkerD test versus SOC through: slower DKD stage progression; delayed or avoided dialysis and transplants; and reduction in dialysis crashes.
- The model also evaluated the potential relative costs associated with PromarkerD, including: PromarkerD test costs every 12, 8 or 6 months for low-, moderate-, and high-risk patients, respectively;[2] costs of preventative medications in high-risk PromarkerD patients (Table 1); treatment costs for each DKD stage, including costs associated with dialysis and transplant (Table 1).

Figure 1. Prognosis of CKD by GFR and albuminuria category.

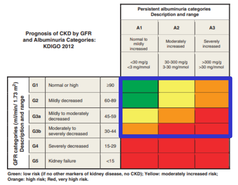


Table 1. Annual Costs per Patient at Each DKD Stage.[6-11]

Cost per Patient at Each DKD Stage	Annual Treatment Cost (USD)	Preventative Medications (PromarkerD High-Risk Patients) (USD)
Stage G1	$16,257	$1,031
Stage G2	$18,288	$1,421
Stage G3a	$21,068	$1,450
Stage G3b	$30,800	$2,082
Stage G4 (Non-Target)	$40,537	N/A
Stage G5 (Non-Target)	$70,219	N/A
ESRD		N/A
Treatment costs	$109,783	
Dialysis	$70,959	
Additional cost of dialysis crash	$49,199 one time	
Transplant	$262,000 one time	
Post-transplant care	$40,000	

Methods

Model assumptions and parameters were derived from prior literature and PromarkerD clinical studies.

- The prevalence of DKD by KDIGO categories was based on US population data.[12]
- Rates of DKD stage progression were estimated from prior PromarkerD clinical studies.[13,14]
- Only high-risk patients were prescribed preventative medications, with 80% adherence assumed.[15]
- A 20% decline in DKD stage progression due to PromarkerD implementation compared to SOC was used.[16] A range of progression rates were also assessed (5-35%).
- A provisional test price for PromarkerD was set at $150 USD. Test prices of $100 and $200 were also used.
- Preventative medication costs were derived from the difference in medication costs between SOC and recommended medications for high-risk PromarkerD patients.
- Proportion of patients insured by Medicare vs. Commercial insurance was 60% vs. 40%, respectively.
- All savings and costs were inflation-adjusted to 2021 USD. A discount rate of 3% was used.[17]

Results

- Of the 31 million patients tested with T2D and no/mild DKD, 6.8 million were predicted by PromarkerD to be 'high-risk' and received additional preventative medications.
- PromarkerD testing could produce savings for US payers of $473 billion over 10 years, against costs of $89 billion, resulting in **net savings of $384 billion over 10 years** (Table 2).

Table 2. Comparative Savings and Costs of using PromarkerD over SOC.

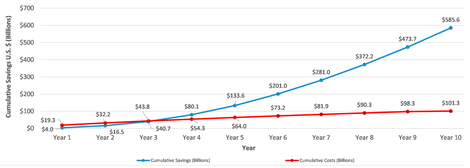
Budget Impact Model (Over 10 years)	Costs (USD)
Savings	$473 billion
Costs	$89 billion
Net Savings	**$384 billion**

- The **total annual savings provided by PromarkerD equal the costs after 2 years.** Savings increase exponentially in subsequent years, far outweighing the associated costs compared to the current SOC without PromarkerD (Figure 2).

Figure 2. Annual (undiscounted) Savings for PromarkerD.

- The **breakeven point occurs at year 3**, after which the total savings are greater than the costs (Figure 3).

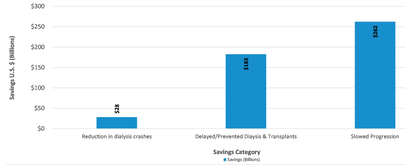
Figure 3. Cumulative (undiscounted) Savings versus Costs of PromarkerD Implementation.



Results

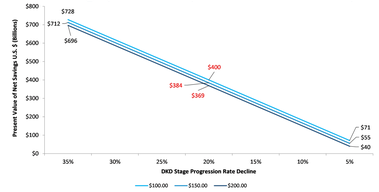
- Over 10 years, **most savings are associated with slowing the progression of DKD** ($262 billion, 55% of total savings), compared to the savings from delaying or preventing dialysis and transplants ($183 billion, 39%), or reduction in dialysis crashes ($28 billion, 6%) (Figure 4).

Figure 4. Gross Present Value of Savings over 10 years by Category.



- In sensitivity analysis, assuming a 5% decline in DKD progression rate still resulted in net savings over 10 years ($40-$71 billion with a $100-$200 PromarkerD test). Net savings were also achieved at the 20% progression rate using a PromarkerD test price of $100 ($400 billion) and $200 ($369 billion) (Figure 5).

Figure 5. Net Present Value of Savings (discounted) from PromarkerD Implementation over 10 years.



Conclusions

- This economic study demonstrates that improved management of people with T2D through the use of early, accurate and cost-effective prognosis with the PromarkerD test could result in savings of $384 billion over 10 years to US payers in the treatment of DKD.
- Employing this alternative PromarkerD testing regime over the current SOC would enable proactive early intervention for T2D patients at high-risk of DKD, thereby decreasing the need for expensive interventions such as dialysis and transplants, or unnecessary adoption of new therapeutic treatments in those at low-risk.

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Boston Healthcare Associates was paid to conduct this study as an independent consultant to Proteomics International.