



Proteomics International

LABORATORIES LTD

ASX Release
6 February 2024

ASX code: PIQ

Investor Presentation

Proteomics International Laboratories Ltd (Proteomics International; the Company; ASX: PIQ) is pleased to release a copy of the presentation to be provided by Dr Richard Lipscombe to delegates at Euroz Hartleys Healthcare Forum being held on 6 February 2024.

Authorised by Dr Richard Lipscombe (Managing Director) and Mr Neville Gardiner (Non-Executive Chairman) on behalf of the Board of PIQ.

ENDS

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.

For further information please contact:

Dr Richard Lipscombe
Managing Director
Proteomics International Laboratories Ltd
T: +61 8 9389 1992
E: enquiries@proteomicsinternational.com

Dirk van Dissel
Investor Relations & Corporate Advisor
Candour Advisory
T: +61 408 326 367
E: dirk@candouradvisory.com.au

Lisa Barnes
Public Relations
Profile Media
T: +61 416 583 672
E: lisab@profilemedia.com.au

Kyle Moss
Corporate Advisor
Euroz Hartleys
T: +61 8 9488 1400
E: kmoss@eurozhartleys.com

Proteomics International Laboratories Ltd

ABN 78 169 979 971

Box 3008, Broadway, Nedlands, WA 6009, Australia

T: +61 8 9389 1992 | E: enquiries@proteomicsinternational.com | W: www.proteomicsinternational.com



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LABORATORIES LTD

Euroz Hartleys 2024 Healthcare Forum

Investor Presentation

6 February 2024

Dr. Richard Lipscombe
Managing Director

Disclaimer



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This Presentation is provided by Proteomics International Laboratories Ltd (Proteomics International, Proteomics, the Company, ASX: PIQ).

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A medical technology company at the forefront of precision medicine and predictive diagnostics

Three key focus tests driven by a proprietary platform technology:

PromarkerD

Diabetic Kidney Disease

COMMERCIALISATION

- Proven predictive test for early detection of diabetic kidney disease (DKD)
- Being commercialised & launched in the US by Sonic Healthcare USA
- US\$390 indicative test price & PIQ receives royalty for each test sold

PromarkerEndo

Endometriosis

DEVELOPMENT

- Test in development to diagnose Endometriosis
- Affects 1 in 9 women and costs Australia alone over AU\$10Bn a year
- Prototype test identified up to 90% of patients with the disease

PromarkerEso

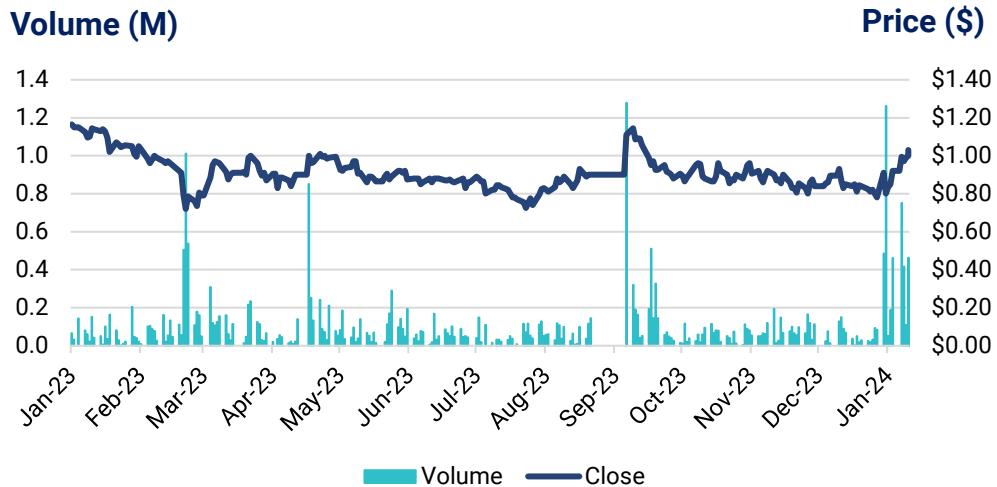
Esophageal Cancer

DEVELOPMENT

- Test in development to diagnose Esophageal Cancer
- 1 in 20 cancer deaths worldwide due to oesophageal cancer
- Prototype test identified up to 90% of patients with the disease

Corporate Snapshot

ASX code	PIQ
Market Capitalisation (Post January '24 Placement)	A\$135m
Cash (31 Dec 2023 + Placement Proceeds)	~A\$11m
Share Price (2 Feb 2024)	A\$1.03
Shares on issue (Post January 24 Placement)	131m
Revenue & other income – H1 FY24	A\$2.3m
Average Quarterly cash burn – H1FY24	A\$1.6m

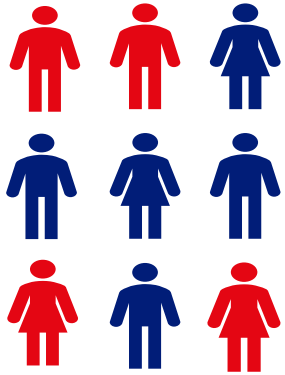


Financial and Corporate

- Top 40 Shareholders hold 54%
- Directors are highly aligned with shareholders holding 14%
- Institutional placement raised \$6.5m with leading Asian and Australian funds participating [ASX: 23 January 2024]
- State-of-the-art laboratories
 - Accredited (ISO 17025 and ISO 13485) cutting-edge facility
 - Specialist proteomics technology platform
 - Analytical services – pharmacokinetic (PK) testing & biosimilars
 - Headquartered on QEII Medical Campus, Perth, WA
- Revenue generating
 - Bioanalytical service business helps offset cash burn
 - Current revenue does not include any major sales of PromarkerD



Promarker™ is a platform technology that can identify unique protein biomarkers ‘fingerprints’

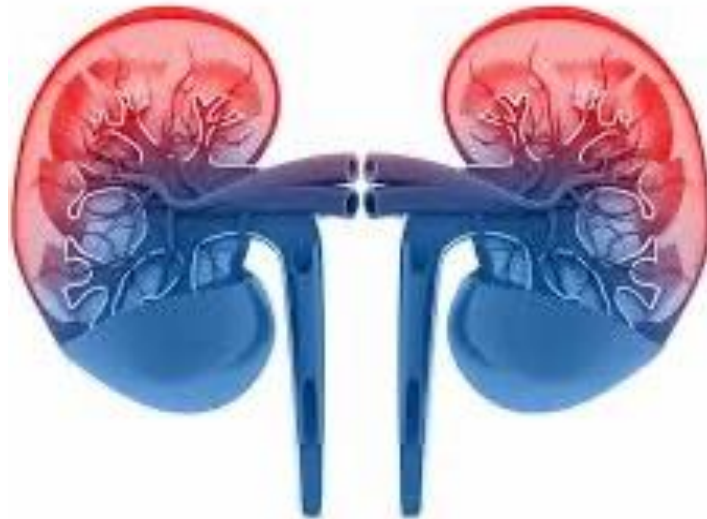


The platform identifies and links the unique protein biomarkers to specific diseases, enabling Proteomics International to create novel diagnostic tests

Promarker **D**

PROACTIVELY CHANGING RENAL HEALTHCARE

A simple blood test for predicting diabetic kidney disease



Problem and Solution – Diabetic Kidney Disease



The Problem

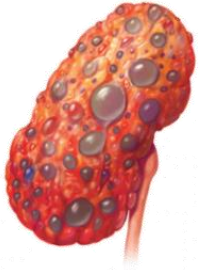
- **537 million adults** with diabetes globally
- **1-in-3** with diabetes have chronic kidney disease
- **Kidney disease is a silent killer** - kidney function can **fall below 15-20% with no symptoms**
- Damage to kidneys is **irreversible**, therefore **early detection** is paramount
- Diabetic kidney disease leads to renal failure which requires **dialysis (US\$72,000 p.a.) or kidney transplant**
- Total cost of diabetic kidney disease = **US\$130 Bn** per year in USA alone



Roadblock

Current standard-of-care diagnostics

- Existing tests (known as eGFR and ACR) can only detect chronic kidney disease once it is already present
- Current standard-of-care tests cannot **predict** the onset of diabetic kidney disease
- **If unchecked, patients ultimately require dialysis and/or a kidney transplant**



Diseased Kidney

Promarker **D**


- PromarkerD can **predict** the onset of disease **before** clinical symptoms appear (up to four years prior)
- **Doctors can then prescribe an early therapeutic treatment to slow or stop the onset of disease**
- Kidneys remain healthier for longer, **saving healthcare systems billions of dollars and improving quality of life** for patients






Healthy Kidney



PromarkerD Global Rollout: Key Highlights





Intellectual Property  Patents granted in all major jurisdictions - PromarkerD Patent family & Trademark covers **72%** of world's diabetics

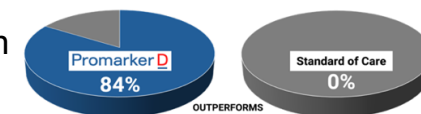
Regulatory  **CE Mark** (EU) registration received for the PromarkerD Immunoassay IVD 
Secured ISO 13485 certification for the manufacture of medical devices
US sales utilising the Lab Developed Test (LDT) pathway via CLIA certified laboratories


Manufacturing scale-up  ISO 13485 certified EU manufacturer
Simple technology platform (immunoassay) – easy to use and integrate into existing pathology lab processes


Peer Reviewed  PromarkerD tested on over **5,000 patients** in 4-year clinical studies
Global multi-centre clinical study (CANVAS) on 3,568 participants in collaboration with Janssen (J&J) 
Clinical & analytical validity proven (Sensitivity 86%); 10+ Peer Reviewed Publications


Physician Support  Clinical utility demonstrated - US based survey showed **96%** of physicians were likely to use PromarkerD test scores for clinical decision making; PromarkerD consistently ranked as one of the top 2 factors driving physician decision-making.

Outperforms Standard of Care  857 community based patients tested for existing DKD at baseline: 497 had normal kidney function
PromarkerD accurately predicted 84% (N=38); All were missed by Standard of Care tests



The Need  **Economic Cost:** Chronic Kidney Disease cost Australia A\$9.9bn in 2021 (Kidney Health Australia) - investment in early detection could yield a net benefit of \$10.2bn over 20 years; Kidney Research UK have declared a public health emergency - by 2033 kidney disease risks costing the UK economy £13.9bn annually

The Treatments  New renal protective therapies: SGLT2-inhibitors approved & potential use of GLP-1 agonist semaglutide (Ozempic)
PromarkerD identifies patients for better management of diabetes, adherence to medications, and focus on diet & exercise

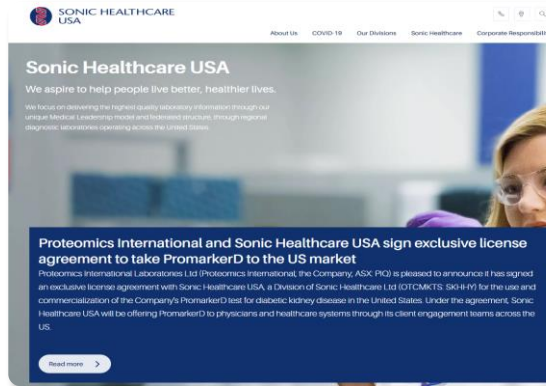
The Utility  **Complementary diagnostic** - Early diagnosis of DKD using PromarkerD can help inform doctors' treatment decisions to improve clinical outcomes for patients. Actions taken BEFORE the onset of DKD

United States: Commercialisation in Progress

Sonic Healthcare USA has the exclusive licence to commercialise PromarkerD in the world's largest healthcare market



Over 7,000 Employees
Over 300 Sales reps
Over 400 pathologists
Services over 20 million patients



Marketing, Sample collection, Reporting



**PromarkerD Diabetic
Kidney Disease Risk
Assessment**

Early detection can significantly help prevent serious kidney damage.

CLIA Certified Laboratories

Sonic is the third Largest laboratory medicine company in the US



Test listed on Sonic website & commercial launch expected in Q2 CY24



Sonic has labs spanning from Hawaii to Boston



Reimbursement in the US



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Proteomics International has worked with its partner Sonic Healthcare USA to achieve reimbursement in the US

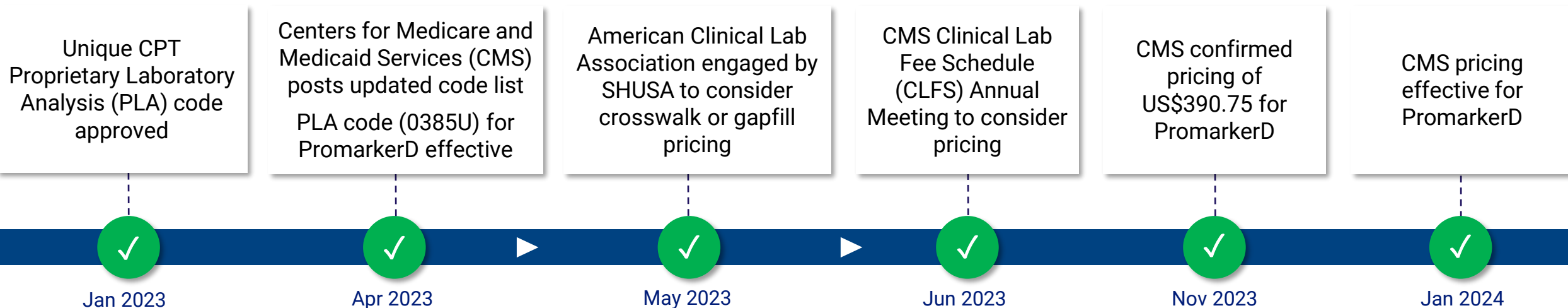
CMS is the federal agency in the United States that administers Medicare and Medicaid

Medicare and Medicaid collectively responsible for 42% of healthcare spending in the US

CMS has assigned a payment rate of US\$390.75 for PromarkerD

CMS is responsible for providing healthcare coverage to more than 100m Americans

US Reimbursement Timeline



Proteomics International will receive a royalty on each test sold

Target Markets: PromarkerD

Proteomics International is showcasing PromarkerD with KoL's at major conferences globally



United Kingdom
4.8m T2 diabetics

- **Distribution Licence with Apacor Ltd** for PromarkerD
- Test registered with Medicines & Healthcare products Regulatory Agency
- *National Institute for Health & Care Excellence (NICE) Medtech Innovation Briefing "NICE Advice" published*

Next Steps

- Engagement with the NHS Supply Chain Tender
- PromarkerD inclusion in the NICE guidelines
- MIB guide healthcare industry, enabling positive engagement with private healthcare providers



Puerto Rico, Chile & Dom Republic
3m T2 diabetics

- **Licence with Omics Global Solutions** for immunoassay (Innovatio ND2): Puerto Rico, Dominican Republic, and Chile
- Test registered with Ministry of Health
- *First sales commenced*

Next Steps

- Securing public reimbursement (Puerto Rico linked to CMS pricing)
- Expanding uptake of the test through engagement with primary care physicians
- *Exploring additional sales to neighbouring territories*



Germany, France, Spain
15.1m T2 diabetics

- PromarkerD is CE Mark registered in Europe
- Germany, France and Spain are initial target markets
- Options to commercialise PromarkerD via:
 - Distributor Model; and/or
 - Licensing Model

Next Steps

- Actively targeting potential partners in key jurisdictions



Rest of World
316m+ T2 diabetics

- Detailed market assessments completed; discussions ongoing

Next Steps

- Actively targeting potential partners in key jurisdictions

Pipeline of Precision Diagnostics

Platform technology drives deep pipeline of novel diagnostic tests

Further global potential in new markets

- Promarker™ platform develops novel intellectual property
- Targeting new diagnostic tests in areas of significant unmet need
- Enormous markets and revenue potential

DIAGNOSTICS RESEARCH AND DEVELOPMENT – THE PROMARKER™ PIPELINE



Dx Pipeline: Endometriosis

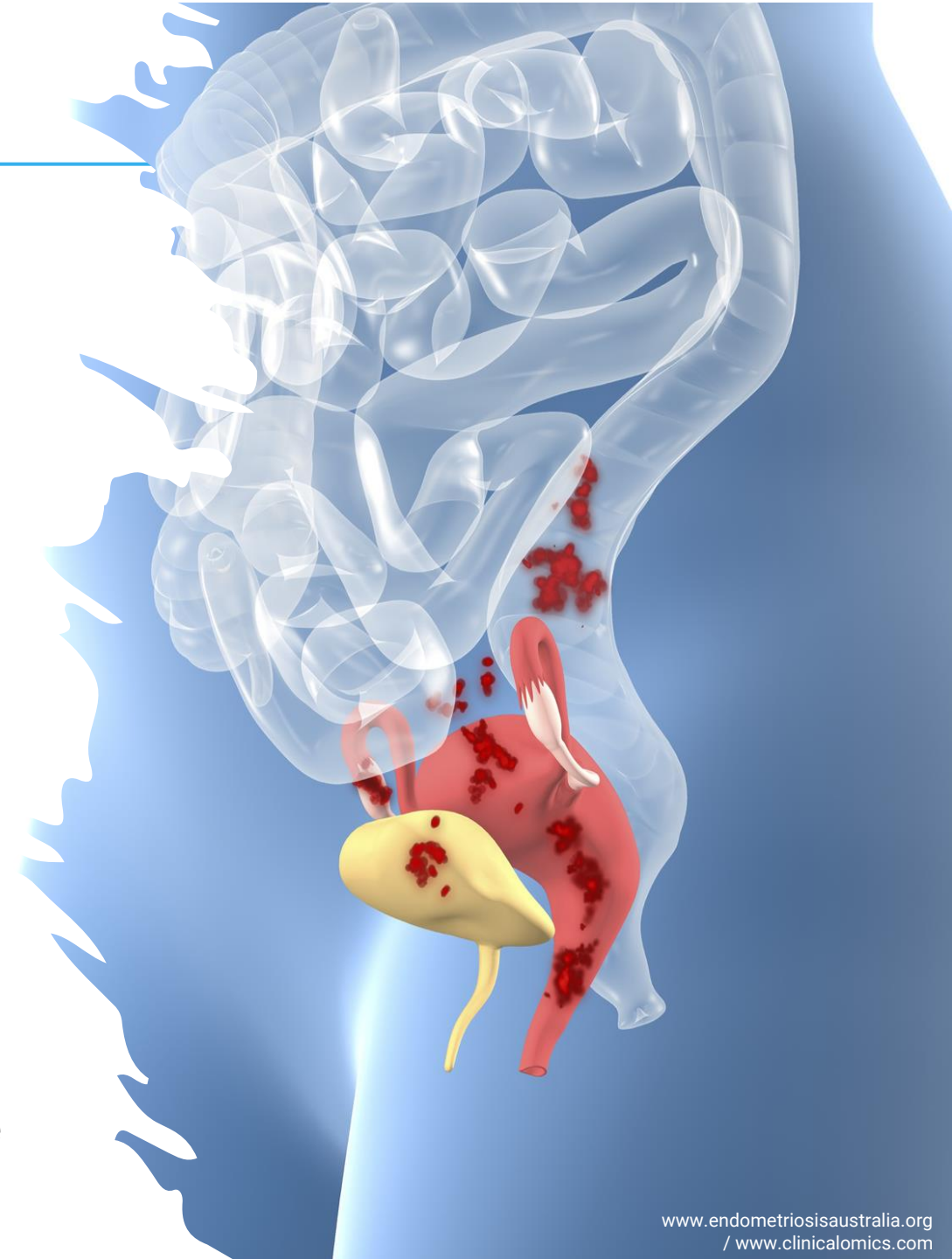
Potential world-first blood test in late-stage development

Impact of Endometriosis

- Endometriosis is a common and painful disease where uterus tissue grows into other organs
- Currently **diagnosis takes an average of 7.5 years** and requires invasive surgery (laparoscopy)
- **Affects 1 in 9 women** and **costs Australia over AU\$10 billion a year** – global opportunity significantly higher

Promarker™ for Endometriosis

- **Prototype test identified up to 90%** of patients with the disease
(World Endometriosis Conference, May '23)
- Collaboration with Royal Women's Hospital & University of Melbourne analysed 901 patients
- Biomarker panel clinically validated in independent patient group
- Biomarkers identified via the Promarker™ platform offer a **potential world-first blood test for endometriosis**
- **Next steps:** Accessing additional samples to confirm clinical performance – Pivotal results anticipated mid CY24



Dx Pipeline: Oesophageal Cancer

Potential world-first blood test in late-stage development

Impact of Oesophageal Cancer

- **1 in 20 cancer deaths worldwide** due to oesophageal cancer
- **5 year survival rate < 20%**
- Currently diagnosis requires a specialist endoscopy procedure; **treating the disease cost \$2.9bn in USA in 2018**
- Test targets oesophageal adenocarcinoma and Barrett's oesophagus (pre-malignant) which affects 1-2% of adults and can **arise from chronic acid reflux**

Promarker™ for Oesophageal Cancer and Barrett's esophagus

- **Prototype test identified 90%** of people with & without the disease
(World Congress Esophageal Diseases, Sept '23)
- Collaboration with QIMR Berghofer Medical Research Institute **analysed 302 samples** across two patient cohorts
- Biomarker panel clinically validated in second independent patient group
- Results indicate a **potential world-first blood test to screen for oesophageal cancer**
- **Next steps:** PIQ has accessed samples from Victoria Biobank to confirm clinical performance – Pivotal results anticipated mid CY24

Timeline & Milestones

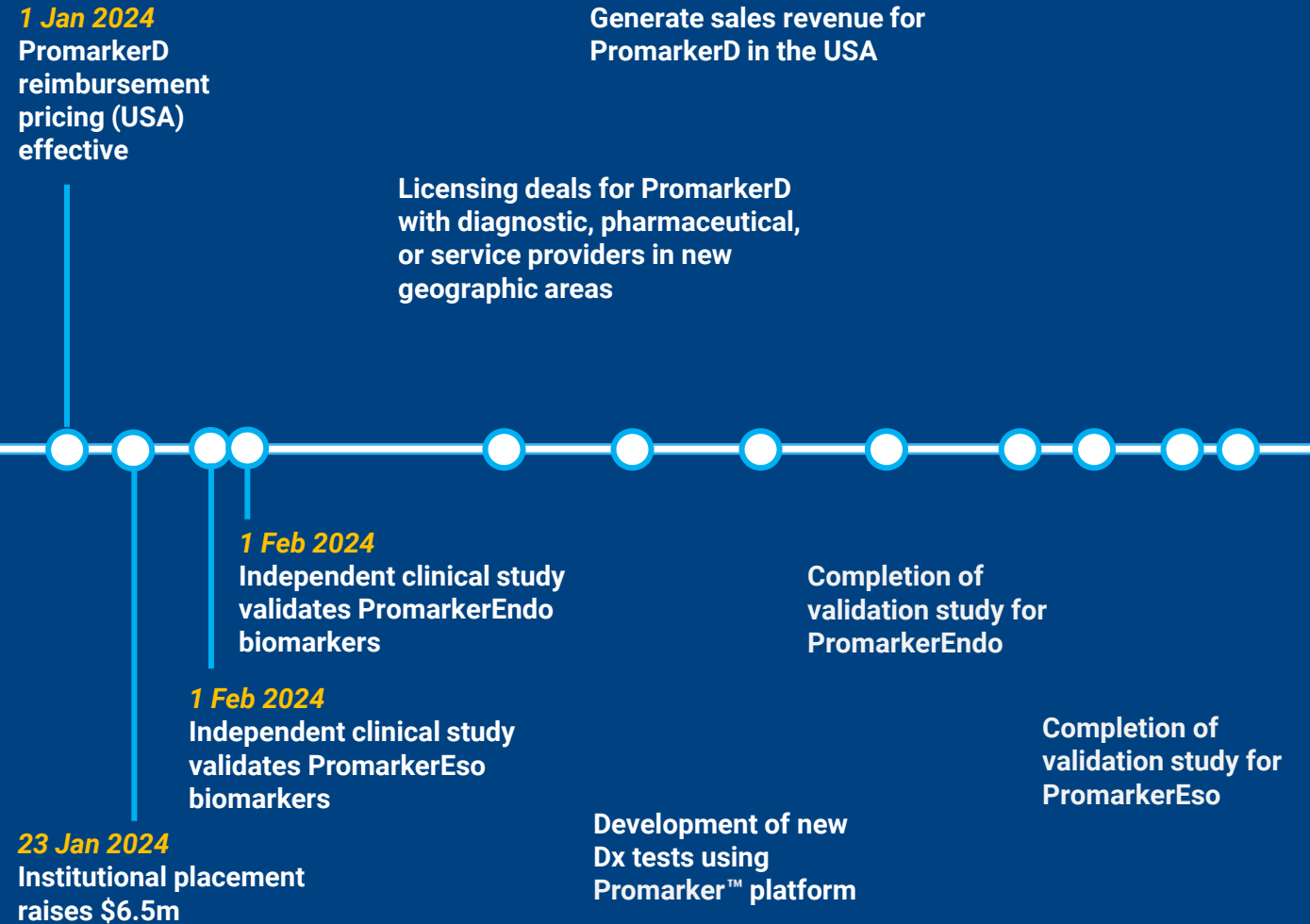


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CY23 Key Milestones



CY24 Achievements & Targets



Value Inflection Points



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Exceptional Global Opportunity

- Disruptive, cutting-edge technology & proven in-house diagnostics platform
- PromarkerD test de-risked, patented, revenue ready
- Test rolling-out in easy-to-use, scalable, low cost format with high margins
- Whole of market appeal: pharma, clinical pathology labs, diagnostic platform developers, diabetes service providers, physicians and patients
- Deep pipeline of potential globally significant tests in development
- Vibrant corporate activity in the precision medicine, diagnostics and CRO (clinical trials) sectors

Share Price Catalysts throughout FY24

Milestone	Qtr	Mar	Jun	Impact
PromarkerD				
First Sales in USA			■	Initiate pathway to significant revenues
Licensing Deals in RoW		■	■	Drive global uptake and future revenue
Regulatory submissions, approvals & Reimbursement RoW		■	■	Build user confidence in product & assist in global roll-out
Promarker™				
Endometriosis Dx – updates		■	■	New first-in-class diagnostic test
Oesophageal Cancer Dx - updates		■	■	New first-in-class diagnostic test
Diagnostics Pipeline - updates		■	■	New IP (validation & proof of concept results)
Analytical Services				
New Contracts		■	■	Engages potential future partners & enhances revenue profile

Dr Richard Lipscombe

Managing Director

T: +61 8 9389 1992

E: enquiries@proteomicsinternational.com

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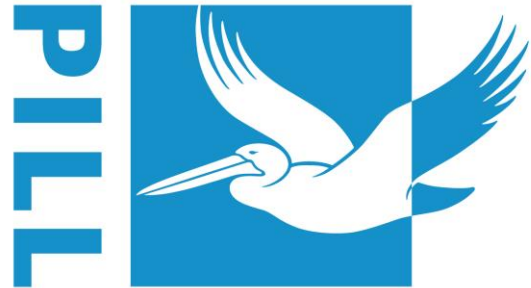
Dirk van Dissel

Investor Relations & Corporate Advisor

Candour Advisory

T: +61 408 326 367

E: dirk@candouradvisory.com.au



Proteomics International

LABORATORIES LTD

Kyle Moss

Corporate Advisor

Euroz Hartleys

T: +61 9488 1400

E: kmoss@eurozhartleys.com

Supplemental



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Board of Directors



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Neville Gardiner BBus (Accounting and Business Law) (Curtin), Non-Executive Chair

Seasoned finance professional with over 30 years' experience providing corporate advice to Boards of public and private companies. He was Co-Founder and MD of Torridon Partners, an independent corporate advisory firm, which was acquired by Deloitte in 2016, where he became Partner in their M&A Advisory team.



Dr Richard Lipscombe PhD (London), MA (Oxon), Co-Founder & Managing Director

Led the Company from foundation through listing in 2015 to today. 30 years biotechnology experience in R&D and product commercialisation in academic and commercial entities. Technical expertise in chemistry, immunology, biomarker discovery & clinical proteomics.



Roger Moore R (Denmark), BPharm (U.Syd), Non-Executive Director

International pharmaceutical industry experience spanning 40 years, including almost 30 years as President of Novo Nordisk Japan. From 2000, he was appointed Novo Nordisk's Senior Vice President, Japan & Oceania Region. He has also served as a member of the Senior Management Board, Novo Nordisk A/S.



Paul House GAICD, BCommerce (UWA), Non-Executive Director

Over 25 years with multi-national corporations, CEO of Imdex (ASX:IMD), prior role as MD of SGS India for 8 years. Previously held CFO and COO roles, and was Senior Manager at a leading global management consultancy firm.



Dr Robyn Elliott PhD Inorganic Chemistry (Monash), BSc(Hons) Chemistry (Monash), Non-Executive Director

Proven track record in product development, clinical trials, regulatory affairs, audits, quality management, project management and operational strategy. Dr Elliott is Executive Director, Strategic Fractionation Program Delivery at CSL Behring, a subsidiary of CSL Limited. She is also a non-executive director of PolyNovo Limited (ASX:PNV).

PromarkerD: World Class Advisory Board

Proteomics International is supported by an international, highly acclaimed advisory board

Professor Tim Davis MedSc, MB, W.Aust., DPhil Oxf., FRACP, MRCP (UK) – *Australia*

Consultant physician and endocrinologist, Fremantle Hospital, Professor of Medicine, University of Western Australia; WA Health Department's Diabetes & Endocrinology Clinical Network Co-lead



Dr Ele Ferrannini MD – *Italy*

Professor of medicine, The University of Pisa
Adjunct Clinical Professor of Medicine, University of Texas Health Science Center: Senior research associate, National Research Council's Institute of Clinical Physiology



Ms Davida F. Kruger MSN, APN-BC, BC-ADM – *United States*

Certified Nurse Practitioner, Henry Ford Health
Past Chair of the American Diabetes Association's (ADA) Research Foundation; ADA Educator of the Year (2017)



Dr Joshua Neumiller PharmD, CDCES, FASCP, FADCES – *United States*

Professor of Pharmacotherapy, Washington State University
Recipient of Albert B. Prescott Pharmacy Leadership Award (2016)
ADCES Diabetes Care & Education Specialist of the Year (2021)



Associate Professor Michael Shanik MD, FACP, FACE – *United States*

Managing partner at Endocrine Associates of Long Island, PC
Clinical Associate Professor, Stony Brook University Hospital, New York



Dr Neil Skolnik MD – *United States*

Professor of Family and Community Medicine, Sidney Kimmel Medical College, Thomas Jefferson University
Associate Director, Family Medicine Residency Program
Jefferson Health



Professor Merlin Thomas MBChB, PhD, FRACP, FAAHMS – *Australia*

Nephrologist, scientist and program leader, the Department of Diabetes, Monash University
Founder and Chief Scientific Officer, RAGE Biotech Ltd



Dr Alexander Turchin MD, MS – *United States*

Director of quality for the division of endocrinology, Brigham and Women's Hospital, Boston
Associate Professor of Medicine, Harvard Medical School
Fellow of the American College of Medical Informatics



Ms Hope Warshaw MMSc, RD, CDCES, BC-ADM, FADCES – *United States*

Registered Dietician, Certified Diabetes Care and Education Specialist
President of the ADCES 2016 & Chair of the Academy's Foundation 2022-2023

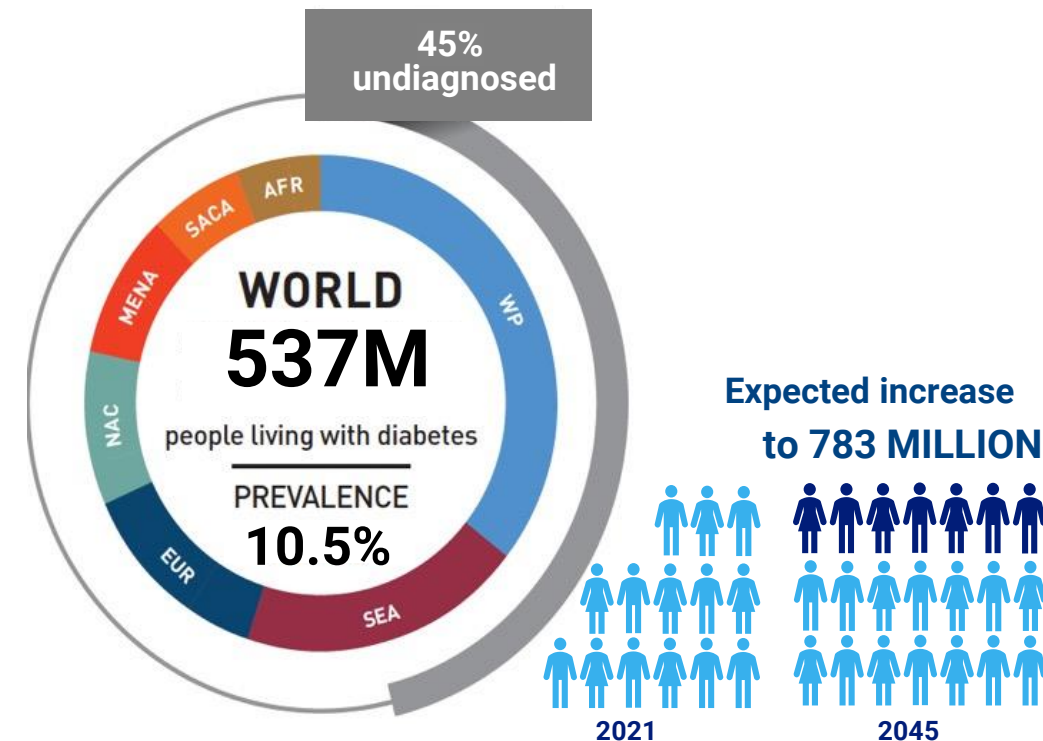


PromarkerD - Patented in all Major Markets

Diabetic Kidney Disease is becoming one of the largest burdens on healthcare systems globally

Patent family & Trademark covers 72% of world's diabetics¹

Country	Patent/Application No	Patent Status	No. Diabetics ¹
Australia	2011305050	Granted	1,491,800
Brazil	BR112013006740	Granted	15,733,600
Canada	2811654	Granted	2,974,000
China	ZL201180053583.9	Granted	140,869,600
Europe ^{2,3}	3151012	Granted	61,425,100
Hong Kong	18115912.3	Granted	686,000
India	3012/DELNP/2013	Granted	74,194,700
Indonesia	W00 2013 01585	Granted	19,465,100
Japan	2013-528474	Granted	11,005,000
Russia	2596486	Granted	7,392,100
Singapore	188527	Granted	711,800
USA^{2,4}	US 9,146,243	Granted	32,215,300
			~368 million Total

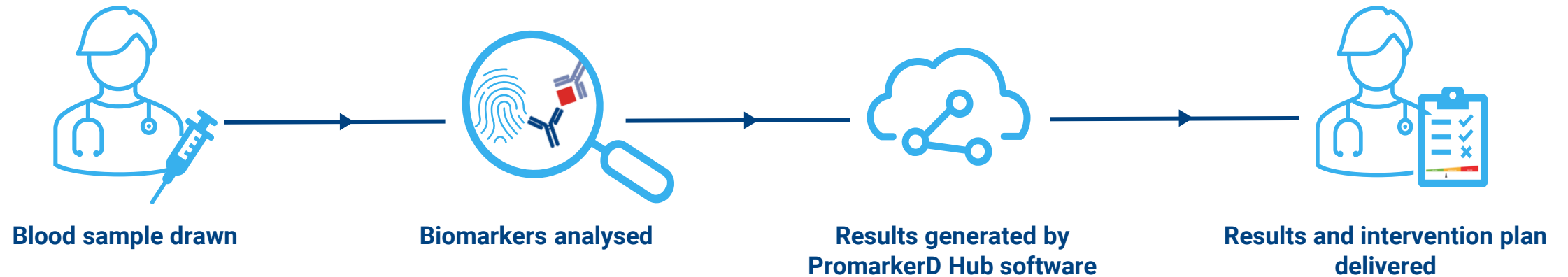


Market assumptions

- Test is performed **once per year per patient** on average
- Standard industry **royalty rates range from 5-15%**

1. International Diabetes Federation (IDF) Atlas 10th Edition 2021 [Age group 20-79 years]
 2. Australia, Europe, HK, USA patent family also covers testing for any form of kidney disease (Extra efficacy studies required)
 3. Covers France, Germany, Italy, Spain, Turkey and the United Kingdom
 4. USA patent further extended to cover method for identifying drugs for abnormal kidney function using one of the PromarkerD biomarkers (CD5L)

PromarkerD – Simple Integration & Use



Sample is drawn at clinic or pathology laboratory

Laboratory uses a standard technology platform
Advanced rapid immunoassay measures three plasma proteins -

combined with three simple clinical factors (age, cholesterol, eGFR)

CE Mark registered

Manufactured to ISO 13485 standard in Europe

Cloud based algorithm, the “PromarkerD Hub” calculates the patient’s kidney disease risk score

Employs a traffic light system for optimal performance, classifies patients as:

- low risk
- moderate risk
- high risk

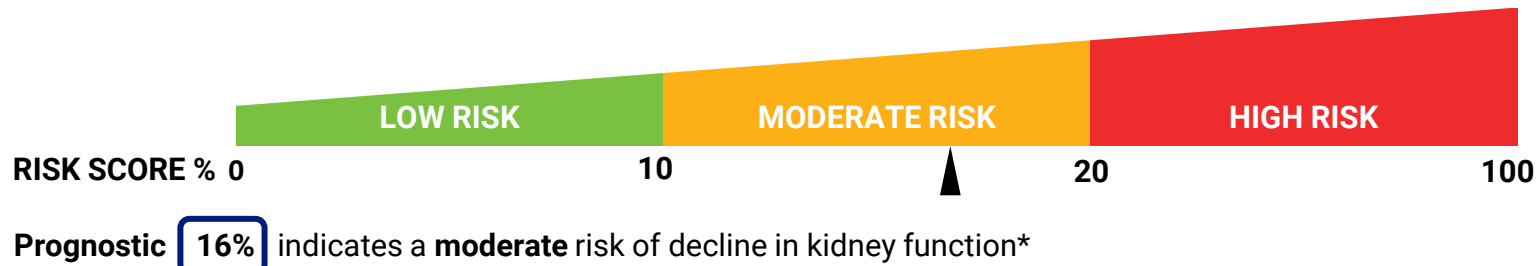
Clinician delivers results to patient

Depending on results, intervention may include:

- change of lifestyle; and/or
- therapeutic drugs
 - SGLT2-inhibitor
 - GLP-1 agonist

PromarkerD – Results & Intervention

How PromarkerD results are delivered



Risk Score	Intervention	Testing Regimen
Low Risk	<ul style="list-style-type: none"> Standard diabetes management 	Test Annually
Moderate Risk	<ul style="list-style-type: none"> More frequent monitoring Optimisation of lifestyle Review of glycemic targets and management Review non-glycemic risk factors Avoidance of potentially nephrotoxic drugs 	Test every 6 months
High Risk	<ul style="list-style-type: none"> Very close monitoring Intensive management strategies based on those for 'Moderate risk' above Utilisation of therapeutic drugs 	Test every 3 months

*as defined by incident diabetic kidney disease (eGFR <60ml/min/1.73m²) in the next four years. Note: if eGFR level at the time of the test is already <60ml/min/1.73m², then the risk of a further decline in kidney function is defined as an eGFR decline >30% in the next four years



PromarkerD in the Clinic




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Peer Reviewed

PromarkerD tested on **over 5,000 patients** in 4-year clinical studies

10+ Peer Reviewed Publications

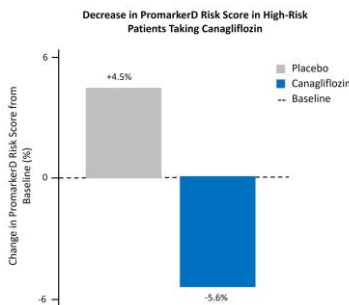
World leading results: 

- Global clinical study 3,568 participants from completed CANVAS clinical trial
- PromarkerD predicted 'incident DKD' high-risk patients **13.5 times more likely** than low-risk to develop DKD ($P = 1.3 \times 10^{-104}$)

[J. Clin. Med. (2020)]

- PromarkerD **high-risk patients show greatest benefit** from early use of SGLT2-inhibitor

[J. Clin. Med. (2023)]



Physician Support

Survey of 400 Endocrinologists & Primary Care Physicians (US based)

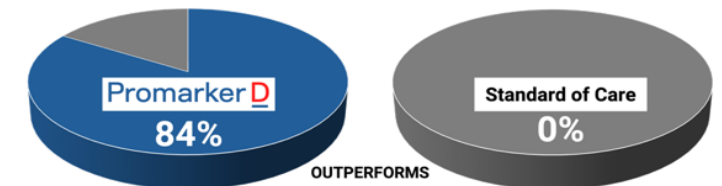
- **96% of physicians** were likely to use PromarkerD test scores for clinical decision making
- PromarkerD consistently ranked as **one of the top 2 factors** driving physician decision-making:
 - monitoring frequency
 - use of anti-inflammatories
 - prescribing SGLT2s
 - ACE inhibitor dosing

[PLOS One (2022)]



Outperforms Standard of Care

- 857 community based patients tested for existing DKD at baseline: 497 had normal kidney function
- 9% of patients developed DKD within 4 years:
 - PromarkerD accurately predicted 84% (N=38)
 - All were missed by Standard of care tests [ASN (2021)]



PromarkerD compared to standard of care tests (eGFR and ACR) for predicting DKD

PromarkerD

The Need

There is a significant and growing need for intervention for diabetic kidney disease (DKD) across the globe

Economic Cost

- Kidney Research UK have declared a public health emergency - by 2033 kidney disease risks costing the UK Economy £13.9 billion annually
- Kidney Health Australia found the annual cost of Chronic Kidney Disease in Australia was A\$9.9 billion in 2021 – investment in early detection could yield a net benefit of \$10.2 billion over 20 years



The Treatments

Patients identified as high-risk of DKD by PromarkerD now have multiple preventative treatment options:

Better management of diabetes

- Adherence to medications
- Focus on diet & exercise

New renal protective therapies

- Three **SLGT2-inhibitors** (empagliflozin, canagliflozin, dapagliflozin) have now been approved for treatment of DKD
- **GLP-1 agonist semaglutide (Ozempic)** trial for DKD shows treatment is renal protective



The Utility

Complementary diagnostic

Early diagnosis of DKD using PromarkerD can help inform doctors' treatment decisions to improve clinical outcomes for patients:

- High-risk patients for kidney decline can be prescribed renal-protective medications such as SLGT2i or GLP-1ag
- Low-risk patients can avoid aggressive treatment options
- Monitor response and change dosage or drug type if required

Actions taken **BEFORE** the onset of DKD

PromarkerD: Key Publications



PromarkerD Demonstrates Benefit of Early Treatment with SGLT2-inhibitors	Peters KE, et al. Canagliflozin Attenuates PromarkerD Diabetic Kidney Disease Risk Prediction Score. J Clinical Medicine. 2023 .
Clinical Utility	Fusfeld L, et al. Evaluation of the clinical utility of the PromarkerD in-vitro test in predicting diabetic kidney disease and rapid renal decline through a conjoint analysis. PLOS ONE. 2022 .
PromarkerD vs Standard of Care	Peters KE, et al. A Comparison of PromarkerD to Standard of Care Tests for Predicting Renal Decline in Type 2 Diabetes. Poster presented at ASN Kidney Week. 2021 .
Economic Health Benefit	Burchenal W, et al. Demonstrating the Economic Health Benefit of using the PromarkerD In Vitro Diagnostic Test in the Prediction of Diabetic Kidney Disease. Poster presented at the American Diabetes Association's 81st Scientific Sessions. 2021 .
Global Multi-centre Validation	Peters KE, et al. PromarkerD Predicts Renal Function Decline in Type 2 Diabetes in the Canagliflozin Cardiovascular Assessment Study (CANVAS). Journal of Clinical Medicine. 2020 .
Predicts Late-stage Renal Function Decline	Peters KE, et al. PromarkerD Predicts Late-Stage Renal Function Decline in Type 2 Diabetes in the Canagliflozin Cardiovascular Assessment Study (CANVAS). Poster presented at ADA. 2022 .
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