



ASX Release  
8 November 2024

ASX code: PIQ

# Proteomics International

LABORATORIES LTD

## AGM Chairman's Address and Investor Presentation

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) is pleased to release a copy of the Chairman's Address to be provided by Mr Neville Gardiner and the Investor Presentation to be provided by Dr Richard Lipscombe to shareholders at the Annual General Meeting to be held in Perth commencing at 9:30 am AWST today.

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](http://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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## Chairman's Address

Good Morning Ladies and Gentlemen

My name is Neville Gardiner, and as Chair of the company it is my pleasure to welcome you to the 10th Annual General Meeting of shareholders of Proteomics International Laboratories.

It is now after 9:30 am, and as we have a quorum of shareholders present, I declare the meeting open.

The notice convening today's meeting was made available to shareholders on the 9<sup>th</sup> of October 2024 and lodged with ASX on that date. Consequently, I will take the notice as read.

Firstly, let me introduce the members of your Board:

With me at the front of the auditorium today are Dr Richard Lipscombe, Managing Director, Dr James Williams, Deputy Chairman and Mr Paul House, Non-Executive Director.

We are joined by Mr Aaron Brinkworth who will be appointed to your Board at the conclusion of this meeting.

Also present here today is Mr James Massie-Taylor representing BDO, our independent auditor.

I would like to especially welcome and acknowledge the many Proteomics team members that are here with us.

Richard will speak in more detail to the company's achievements in FY24 and our plans for FY25 in his presentation after the conclusion of the formal items of business.,

I would like to take this opportunity to thank Dr Robyn Elliott, who retired from the Board on 12 August 2024 and Roger Moore, who retires as at the end of this meeting, for their significant contributions to the company during their tenure and wish them well in their future endeavours.

While we will miss the wise counsel and insights of Robyn and Roger, we are delighted that we have been able to attract two new members to the Board of the calibre of James and Aaron. Their skills and experience are of great value to our company as we embark on the next exciting chapter of our growth.

As announced recently, at the conclusion of this meeting I will hand over the Chairman role to James and look forward to supporting his Board leadership at this important time.

On behalf of the Board, I would like to thank Richard and the entire Proteomics team for their continuing professionalism and dedication. Their hard work has the potential to fundamentally improve millions of lives. I would also like to thank all our shareholders for their continuing support.

I will now turn to the formalities of the meeting.



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# Proteomics International

LABORATORIES LTD

## AGM Presentation

8 November 2024

**Dr. Richard Lipscombe**

Managing Director

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# Disclaimer



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You should not rely upon anything in this presentation and/or any information obtained from the Company, its Directors or their associates in deciding whether or not to seek to purchase the shares of the Company. This is not an offer to subscribe for securities in the Company.

The Presentation may contain quantitative statements of anticipated future performance such as projections, forecasts, calculations, forward-looking statements or estimates all of which are based on certain assumptions (Forward Looking Statements). The Forward Looking Statements may involve subjective judgements and are based on a large number of assumptions and are subject to significant uncertainties and contingencies, many of which are outside the control of the Company and may not prove to be correct.

No representation or warranty is made that any Forward Looking Statements will be achieved, or occur, or that the assumptions upon which they are based are reasonable or the calculations from which they have been derived are correct. Actual future events may vary significantly from the Forward Looking Statements. Each Recipient should undertake their own independent review of the Forward Looking Statements, including the assumptions on which they are based and the financial calculations from which they are derived.

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

## Commercialising three first-in-class tests driven by a proprietary platform technology:

### Promarker<sub>D</sub>

*Diabetic Kidney Disease*

COMMERCIALISATION

- A novel and accurate test for predicting the onset of chronic kidney disease in type 2 and type 1 diabetes (DKD)
- 10.5% of adults worldwide currently have diabetes
- US reimbursement price set at US\$390

### Promarker<sub>Endo</sub>

*Endometriosis*

DEVELOPMENT COMMERCIALISATION

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

### Promarker<sub>Eso</sub>

*Esophageal Cancer*

DEVELOPMENT COMMERCIALISATION

- A novel and accurate test to diagnose esophageal cancer
- 1 in 20 cancer deaths worldwide due to esophageal cancer
- Clinical validation study: test identified 94% of patients with the disease

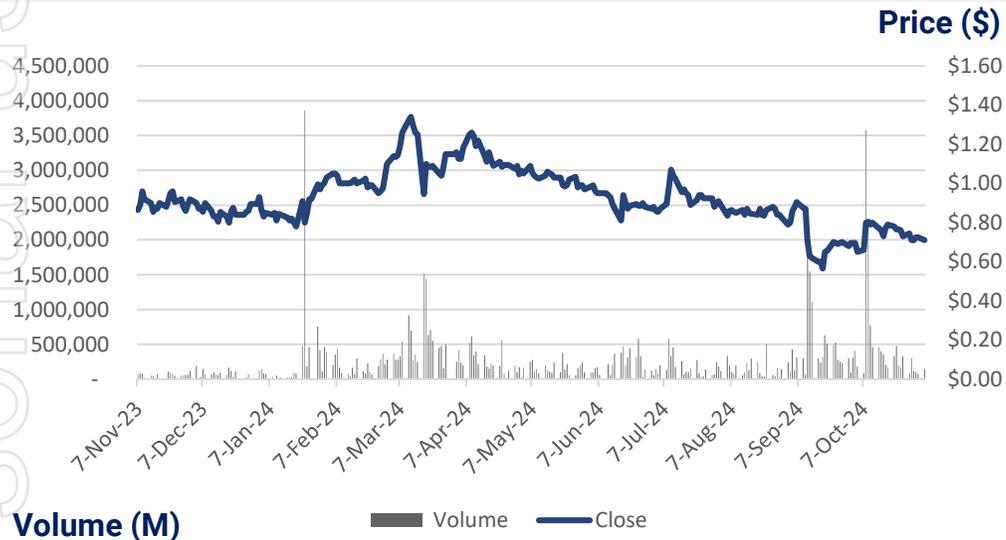
# Corporate Overview



ASX: PIQ

## Corporate Snapshot

ASX code	PIQ
Market Capitalisation	A\$91m
Cash (30 Sept 2024) (+ R&D Tax Incentive ~\$2m H1 FY25)	~A\$5.1m
Share Price (6 Nov 2024)	A\$0.70
Shares on issue	131m
Revenue & other income – FY25	A\$2.7m
Average Quarterly cash burn – FY25	A\$1.5m



## Financial and Corporate

- Top 40 Shareholders hold 41%
- 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 sales of PromarkerD, PromarkerEndo or PromarkerEso
- Corporate
  - Board renewal progressed
  - Finalising recruitment of senior executives to accelerate commercialisation of 3 lead tests

# Science Proven – Commercialisation Underway

## Over 20 years R&D experience resulting in deep pipeline



- 3 highly accurate tests commercialisation ready
- Large unmet medical needs
- Will save patient lives & improve quality of life
- Save healthcare systems billions of dollars

## New commercial opportunities for specialised tests



- Changes to regulatory pathways are opening the door to launching specialised tests
- 320,000 CLIA certified labs in the USA
- Paths: ISO 15189 (Australia); In-house in-vitro diagnostic (IVD) (Europe); Laboratory Developed Test (LDT) (USA)
- PIQ using its expertise to adapt its sophisticated (mass spectrometry) tests for clinical use; by-passing need to create immunoassay (PromarkerD); set-up/train specialised Reference Laboratories
- Example: C2N Diagnostics successful launch of its Alzheimer's test



## Each test has whole of market appeal

- Pharma
- Clinical pathology labs
- Diagnostic platform developers
- Physicians
- Patients



## New, cost-effective routes to market

- Pandemic has changed the landscape: middle-man can now be cut out
- Allows PIQ and their partners to go direct to the patient
- Patients expect virtual testing - telehealth options - the health ecosystem has evolved to support this
- Will allow PIQ to obtain a far greater share of the revenue and have more control of strategy
- Minimal Capex and time required to execute on strategies: ~\$100k's not millions and months not years

# The Problem: target populations for DKD, Endo & Eso

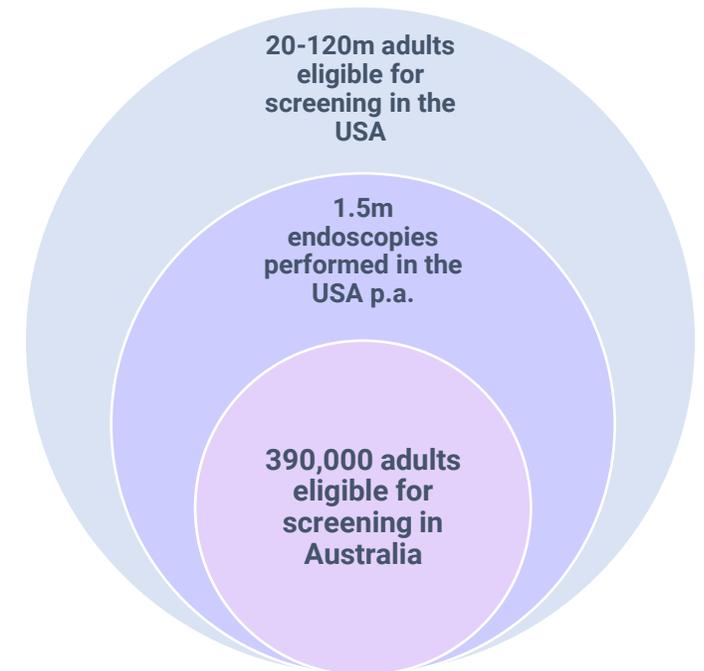
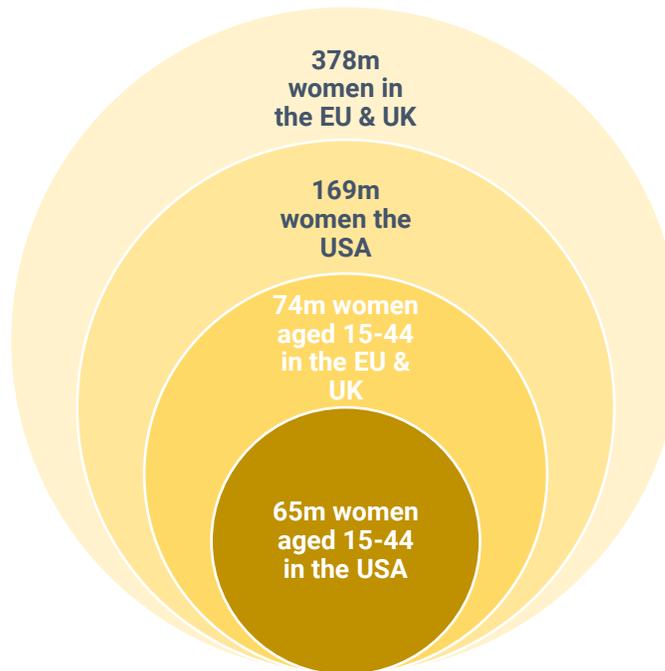
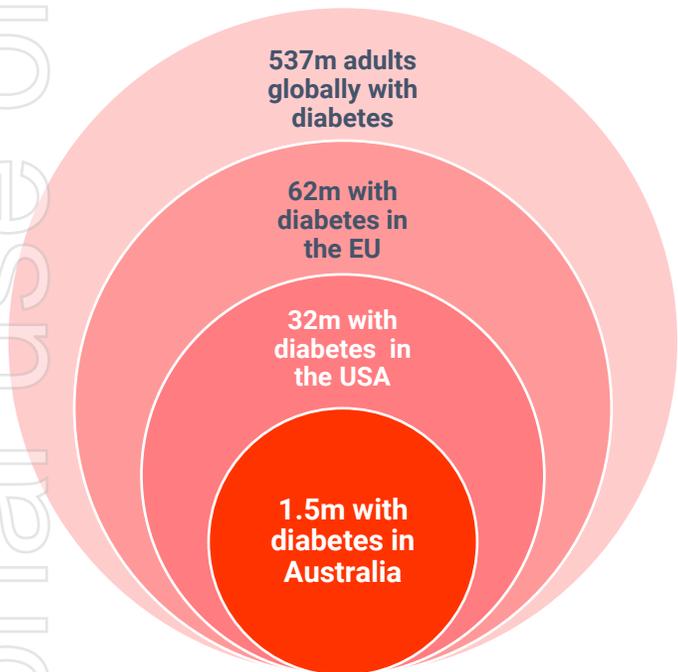


10.5% of global adult population have diabetes

1 in 9 women have endometriosis

1-2% of western populations at risk of Esophageal Cancer

*(Diagnosed by endoscopy with biopsy)*



Sources:  
[www.statista.com/statistics/755225/population-of-europe-bygender/#:~:text=In%202023%2C%20the%20female%20population,male%20population%20of%20358.3%20million](http://www.statista.com/statistics/755225/population-of-europe-bygender/#:~:text=In%202023%2C%20the%20female%20population,male%20population%20of%20358.3%20million)  
International Diabetes Federation (IDF) Atlas 10th Edition 2021 [Age group 20-79 years]  
[www.medscape.com/viewarticle/990519?form=fpf](http://www.medscape.com/viewarticle/990519?form=fpf)  
[www.cancer.org.au/assets/pdf/9-august-2020](http://www.cancer.org.au/assets/pdf/9-august-2020)  
(European Commission)(Statistics Times)(ONS.gov)  
Australian eligible adults screening determined as midpoint of 1-2% of Australian population of ~26m

# The Solution: precision medicine targeting unmet needs



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## Promarker D

### Diabetic Kidney Disease

- **1-in-3** with diabetes currently have chronic kidney disease
- **PromarkerD can predict onset of CKD** up to 4 years in advance – accuracy 86%
- Novel blood test taken yearly on average
- Targeting type 2 and type 1 diabetes
- New therapeutic treatments available – GLP-1 agonists, gliflozin class (SGLT-2s)
- **Targeting Australia Launch Q1 CY25**

## Promarker Endo

### Endometriosis

- Potential **target is all** pre-menopausal women globally
- Currently **diagnosis takes average of 7-10 years**
- Standard of care for diagnosis is invasive surgery
- World-first blood test is ~90% accurate
- Significant community, Government and personal interest in the Endometriosis space
- **Targeting Australia Launch Q2 CY25**

## Promarker Eso

### Esophageal Cancer

- **1 in 20** cancer deaths worldwide due to esophageal cancer
- **5 year survival rate < 20%**
- Novel blood test is 94% accurate
- World-first blood test to screen for esophageal cancer
- Standard of care for diagnosis is endoscopy, which is costly and time consuming
- **Targeting Australia Launch Q1 CY25**

Personal use only

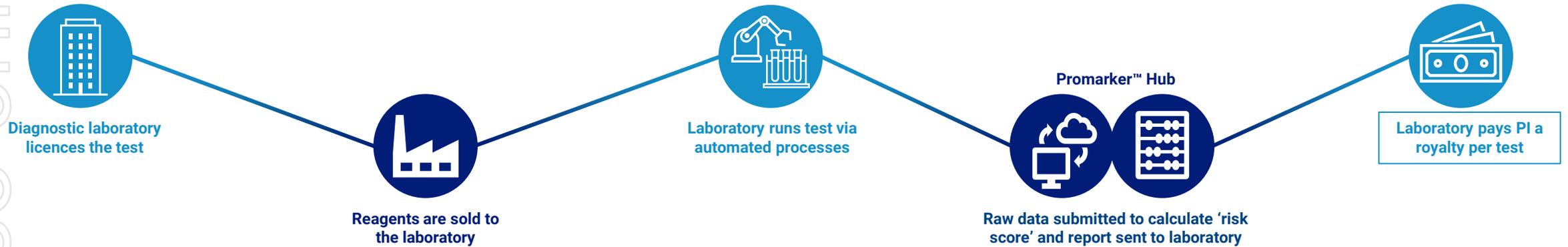
# Go-to-Market Pathways



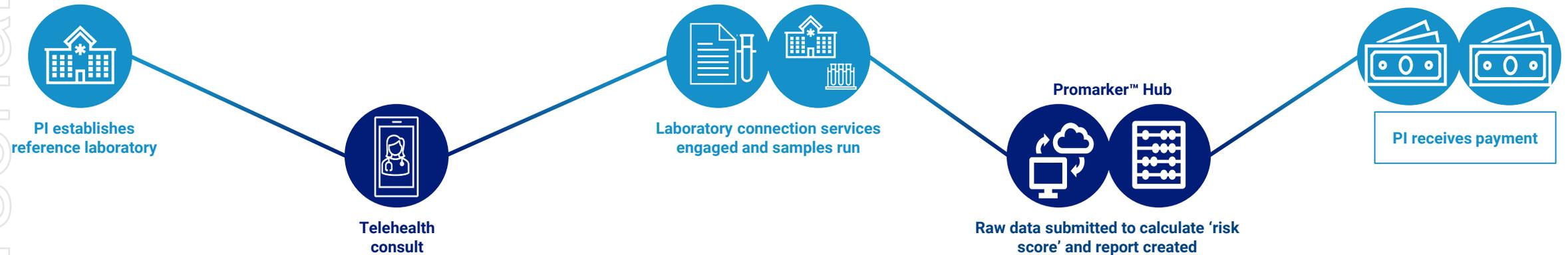
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*Proteomics International is pursuing a hybrid G2M strategy for its suite of novel diagnostic tests*

## Traditional licensing model



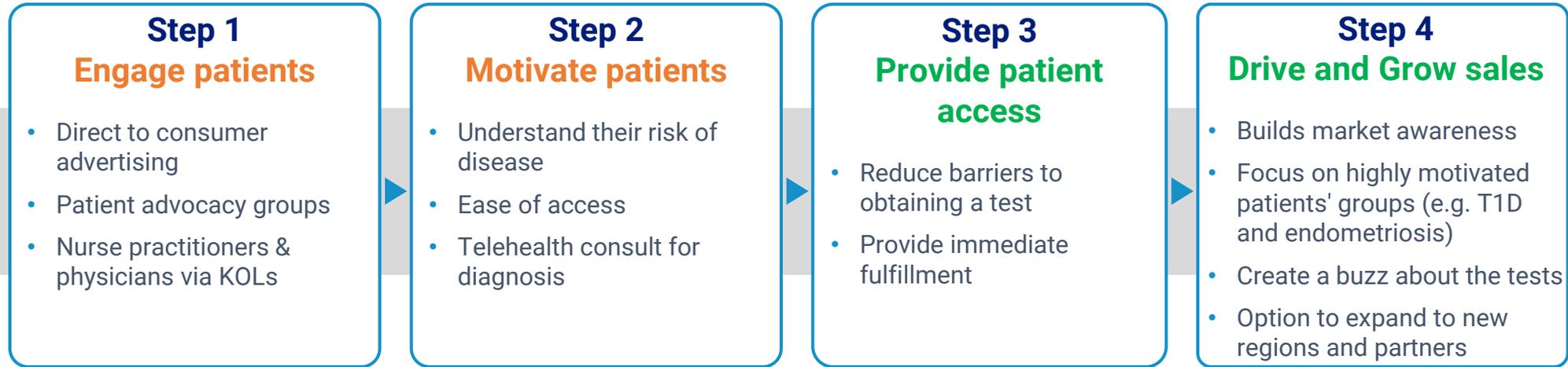
## Direct to consumer/patient (DTC/DTP) and digital marketing pathway



# Launch Strategy for DTP

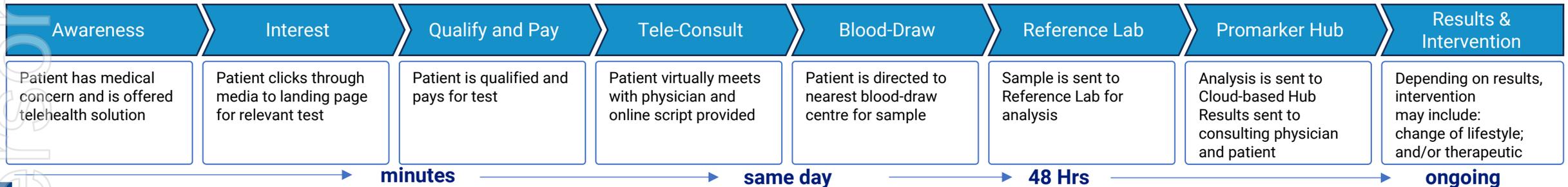
*Establishing first sales via DTP builds product awareness and drives mainstream use and subsequent volume*

**Swiftly position each Promarker test as the key tool for patients & physicians**



- Initial use via self-pay
- Existing PromarkerD PLA code & pricing (in US) provides engagement point for insurers
- Usage builds case for reimbursement of PromarkerEndo and PromarkerEso

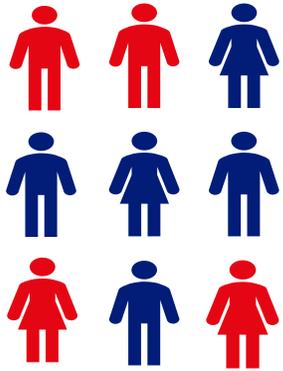
## DTP Significantly speeds up time to diagnoses, treatment & intervention



# Promarker – Platform Technology



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

# Pipeline of Precision Diagnostics

*Platform technology drives deep pipeline of novel diagnostic tests*

## DIAGNOSTICS RESEARCH AND DEVELOPMENT – THE PROMARKER™ PIPELINE



### 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

# PromarkerD Global Rollout – Key Highlights



## Intellectual Property



Patents granted in all major jurisdictions - PromarkerD Patent family & Trademark covers **72%** of the world's diabetes patients

## Regulatory



**CE Mark** (EU) registration received for the PromarkerD Immunoassay IVD  
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

## Breakthrough Study



**PromarkerD validated for Type 1 (T1D) diabetes** - demonstrated **high accuracy** (AUC of 0.93) in predicting chronic kidney disease in patients with T1D (represents 10% of all diabetes cases); Offers a new target market

# PromarkerD: Existing partnerships

*Proteomics International is focused on supporting its partners to achieve first sales in each jurisdiction*



**European Union**  
61m+ T2 diabetics

- PromarkerD is CE Mark registered in Europe
- Detailed market assessments completed

- Current Steps**
- Establish independent Reference Laboratory



**France, Italy, Spain +**  
13.6m T2 diabetics

- **Appointed Growth Medics** as sales agency for Europe, targeting Netherlands, Belgium, Italy and Spain
- **Eurobio Scientific licenced** to sell test in France

- Current Steps**
- Engaging with potential Reference Labs & customers in designated markets
  - Assessing reimbursement pathways
  - Targeting further country partners



**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*

- Current Steps**
- Engaging with potential Reference Labs
  - Engaged with the NHS Supply Chain Tender
  - Targeting PromarkerD inclusion in the NICE guidelines



**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*

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

# PromarkerD in the US: derisked & commercial ready

*Critical milestones have been achieved*

Targeting the 32 million people with diabetes in the USA



Unique Proprietary Laboratory Analysis (PLA) code established  
allows future crosswalk for T1D & T2D versions of test



Centres for Medicare & Medicaid Services (CMS) pricing established  
\$390.75 benchmark pricing for payors



Tech transfer to CLIA Certified Laboratory  
automated systems already operating at PIQ

Clinical Advisory Board established  
world class KOLs representing physicians, specialists, dieticians & nurse practitioners



New PI reference laboratories will support roll-out of all Promarker tests  
Processes built are accelerating path to market for PromarkerEndo & PromarkerEso

# PromarkerEndo: Endometriosis



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## World-first blood test 'PromarkerEndo' nearing commercialisation

Clinical question – can a blood test distinguish between individuals who are:

- 1) healthy
- 2) symptomatic patients (pelvic pain but surgically-diagnosed absence of endometriosis)
- 3) endometriosis patients (confirmed by laparoscopy – 4 stages: minimal/mild/moderate/severe)

### Test status

- **Prototype test identified up to 90%** of patients with the disease  
(World Endometriosis Conference, May '23)
- **Patents pending** in all major jurisdictions
- Prototype test showed limitations in diagnosing symptomatic patients from minimal & mild endometriosis
- Advanced statistical modelling performed to **distinguish symptomatic patients from minimal & mild endometriosis**
- New clinical results **submitted for peer review publication**
- Further model optimisation being finalised using 'traffic light' system to improve test performance for clinical use
- Methodology (mass spectrometry) being **adapted for clinical launch**
- Discussions underway to establish test in reference laboratories in USA and Europe
- Proteomics International preparing **to launch PromarkerEndo in Australia** under ISO 15189 accreditation, targeting **Q2 CY25**

### Clinical studies

- *Development* - biomarker panel (Wesley Medical Research Biobank N=56 samples)
- *Validation* - Collaboration with Royal Women's Hospital & University of Melbourne analysed (endometriosis N=494; healthy individuals N=153; symptomatic controls N=254) (World Endometriosis Conference, May '23)
- *Clinical validation* - biomarker panel confirmed in independent patient cohort from St John of God Subiaco Hospital Gynaecological Cancer Research Group (N=241 patients) (Lorne Proteomics Symposium, Feb '24)
- *Clinical validation* - Collaboration ongoing with University of Oxford for international validation study (N=600 samples)

# PromarkerEso: Esophageal Cancer

## World-first blood test 'PromarkerEso' ready for commercialisation

**Clinical question – can a blood test distinguish between individuals who are:**

- 1) **healthy**
- 2) **esophageal adenocarcinoma (EAC) patients**
  - Only 50% of EAC patients report chronic acid reflux
  - 90% of EAC cases continue to remain undetected
  - 25% of EAC cases misdiagnosed as negative by endoscopy

### Test status

- **Test shows 94% accuracy** in diagnosing patients with and without the disease  
(World Congress Esophageal Diseases, 2024)
- **Patents granted in Europe, China, Australia; USA pending**
- Model optimisation refined using 'traffic light' system to improve test performance for clinical use
- Latest **clinical validation results** presented at World Congress Esophageal Diseases, Sept '24
- Methodology (mass spectrometry) being **adapted for clinical launch**
- Discussions underway to establish test in reference laboratories in USA and Europe
- Proteomics International preparing **to launch PromarkerEso in Australia** under ISO 15189 accreditation, targeting **Q1 CY25**

### Clinical studies

- *Development and Validation* - Collaboration with QIMR Berghofer Medical Research Institute analysed 302 samples across two patient cohorts: (World Congress Esophageal Diseases, 2023)
  - ❑ PROBE-NET study, Australia (N=249)
  - ❑ Ochsner Health System, USA (N=49)
- *Clinical validation* - biomarker panel confirmed in independent patient cohort from Victoria Cancer Biobank (N=165)  
(Lorne Proteomics Symposium, Feb '24)
- *Clinical validation* – ongoing analysis of samples from Victoria Cancer Biobank to confirm clinical performance of the test (N=165)

# Dx Pipeline: Oxidative Stress

## Potential world-first blood test in late-stage development

### What is Oxidative Stress?

- Oxidative stress occurs when the body's antioxidant defences are overwhelmed by an excess of toxic oxidants
- Oxidative stress is implicated in over 70 health conditions with **levels often reflective of a person's health condition**

### OxiDx – blood test to monitor oxidative stress

- OxiDx P/L was spun out of PIQ and the University of Western Australia in Aug 2022

### World first test:

- **Accurate** - highly sensitive
- **Simple to use** – finger prick sample
- **Cost effective** – for mass market use
- **Peer reviewed** – multiple journal publications
- **Patented** – patent families cover Australia & USA, Europe & Japan; others pending

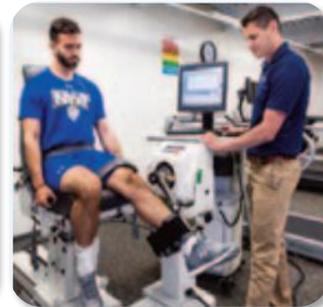
# OxiDx

### Targeting commercial use of OxiDx technology:

- **Athletic monitoring tool for competition preparedness:**
  - **Professional Sports** – performance, recovery and injury risk management – *55% of sports injuries are muscle related*
  - [Proof-of-concept study being finalised](#)
  - **Thoroughbred Racing Industry** – injury risk management and race-preparedness - *85% of Thoroughbreds suffer injury in their first 2-3 yrs*
  - [Proof-of-concept study being finalised](#)

### Potential spin-out opportunity:

- In discussions for third party investment

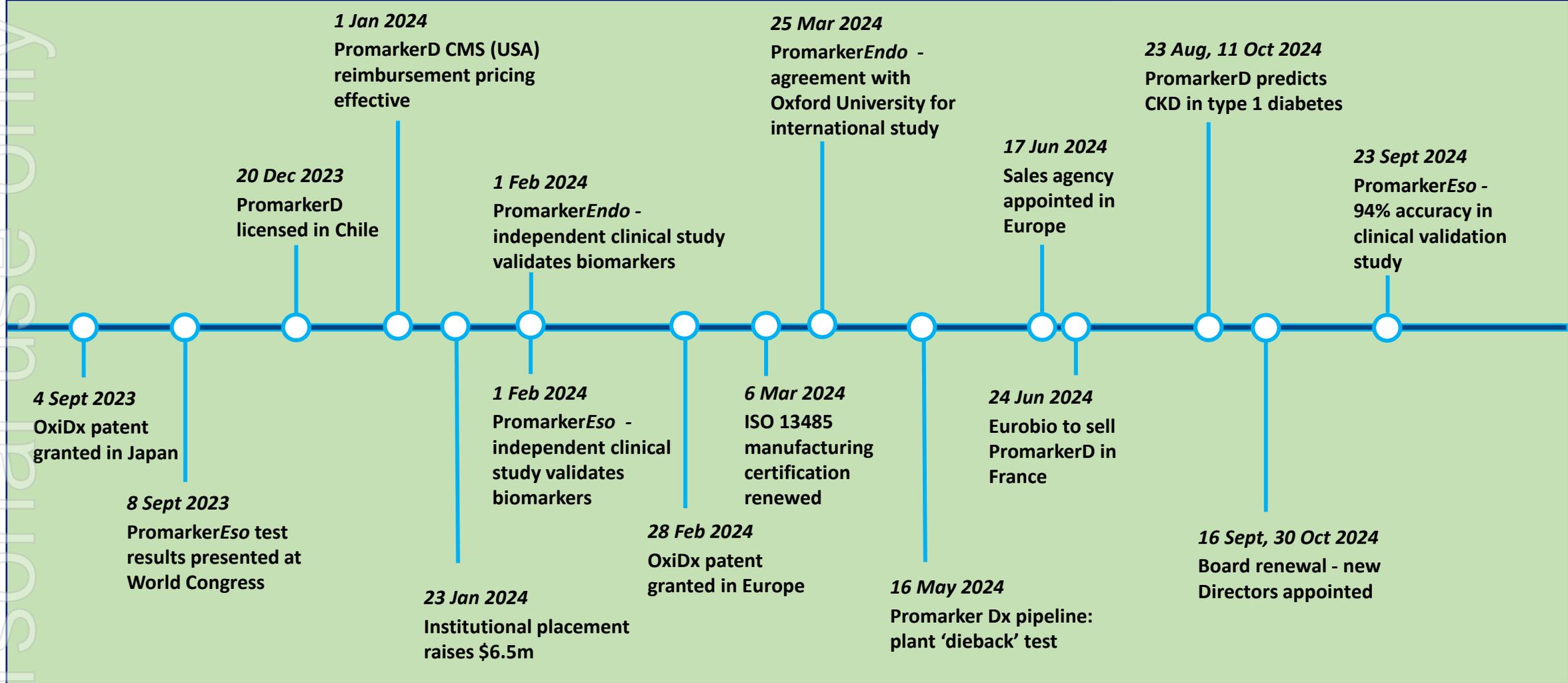


# Timeline & Milestones



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## FY24-25 Achievements



# Multiple Value Drivers in FY25

## Exceptional Global Opportunity

- Disruptive, cutting-edge technology & proven in-house diagnostics platform
- PromarkerD test de-risked, patented, revenue ready
- PromarkerEndo and PromarkerEso tests nearing market entry
- Tests are scalable with high margins
- Whole of market appeal: pharma, clinical pathology labs, diagnostic platform developers, physicians and patients
- Vibrant corporate activity in the precision medicine, diagnostics and CRO (clinical trials) sectors

## Potential Share Price Catalysts throughout FY25

Milestone	TARGET Qtr	Dec	Mar	Jun	Impact
<b>Commercial</b>					
First Sales PromarkerD in USA			█	█	Initiate pathway to significant revenues
PromarkerD launched in Australia			█		Drive global uptake and future revenue
PromarkerD launched in EU		█	█		Route to first sales in each country
PromarkerEndo launched in Australia				█	First sales
PromarkerEso launched in Australia			█		First sales
<b>Clinical/Technical</b>					
Endometriosis Dx - results update		█			New first-in-class diagnostic test
Esophageal Cancer Dx - results update		█			New first-in-class diagnostic test
OxiDx test - results update		█			New first-in-class diagnostic test
<b>Regulatory/Reimbursement</b>					
PromarkerD submissions (TGA, FDA)			█	█	Assist global roll-out
Endo 'FDA breakthrough' submission				█	Support US roll-out
Eso 'FDA breakthrough' submission			█		Support US roll-out

## Dr Richard Lipscombe

### Managing Director

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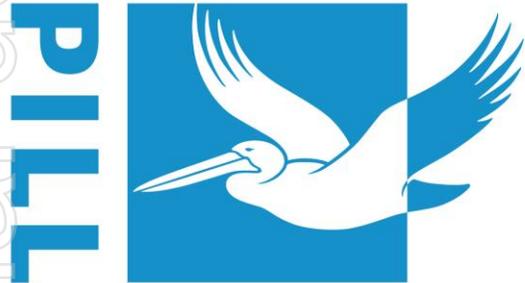
## Dirk van Dissel

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# Proteomics International

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# Farewell



## Dr John Dunlop

10<sup>th</sup> July 1942 - 15<sup>th</sup> December 2023

Inaugural Chair, Proteomics International  
Director, Proteomics International, 2001 – 2018

On 15 December last year, Proteomics International and the Western Australian biotechnology industry lost one of its quiet achievers, Dr John Sutherland Richardson Dunlop. John was a serial entrepreneur and businessman, active across multiple sectors from biotechnology to mining and renewable energy for more than 50 years.

In 1982, John established Western Biotechnology with career-long colleagues Terry Sweet and Dr Bill Parker (both now also former directors of Proteomics International). The company, which was then the world's only producer of natural beta-carotene from algal lakes, was acquired by Hoffmann La Roche, and the plant is still operating today.

In 2001, John became the inaugural Chair of Proteomics International shortly after it was founded by Bill and Dr Richard Lipscombe. John served as a director throughout the company's formative years, only retiring from the board in 2018. John's guidance and steely Scottish pragmatism contributed enormously to Proteomics International's growth and ultimate ASX listing (as PIQ) in 2015.

John was one of life's true gentlemen, who wove his interests into a rich tapestry, from geologist (who also discovered one of the earliest forms of life on the planet in a rock formation in the Pilbara), to family man, rowing coach and Morris dancer. John told it like it was, underpinned with a bone-dry sense of humour. He will be greatly missed by all those who knew him.

# Supplemental

# Board of Directors



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## **Dr James Williams** PhD (Melbourne), MBA (UWA), BSc, Hons (Aberdeen), GAICD, Non-Executive Director & Chair elect

Accomplished manager, director, scientist and investor with experience covering all aspects of life-science technology translation. Involved from startup to commercialisation, including CEO, CTO, Director and Chair roles, of numerous biotech companies (including Dimerix (DXB.ASX) and iCeutica) which have resulted in five Food and Drug Administration (FDA) approved drugs & medical devices.



## **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.



## **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.



## **Neville Gardiner** BBus (Accounting and Business Law) (Curtin), Non-Executive Chair (standing down AGM Nov 24)

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.



## **Roger Moore R** (Denmark), BPharm (U.Syd), Non-Executive Director (retiring AGM Nov 24)

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.



## **Aaron Brinkworth** GAICD, BHLthSc (ECU), Non-Executive Director (appointed 8 Nov 24)

Over a 22-year career at Gilead Sciences, Inc. (Nasdaq: GILD), he held senior commercial, patient access and strategic licensing roles. Mr Brinkworth has led Gilead's Asia Pacific commercial and access operations where he was responsible for developing high performing sales, marketing, and distribution networks across the region. Mr Brinkworth currently serves as non-executive Director for Resonance Health Ltd (ASX: RHT).

# Promarker **D**

PROACTIVELY CHANGING RENAL HEALTHCARE

*A simple blood test for predicting diabetic kidney disease*



# 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



**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 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



**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 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)



**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



**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

# 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 - Patented in all Major Markets

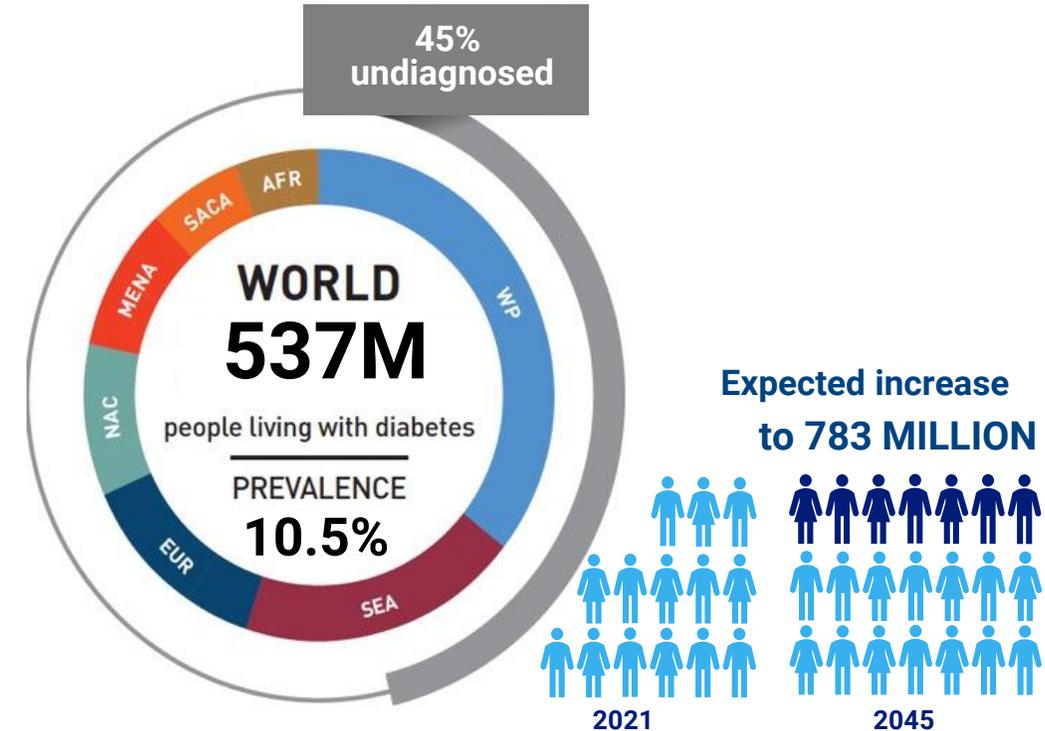


ASX: PIQ

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

Patent family & Trademark covers 72% of world's diabetics<sup>1</sup>

Country	Patent/Application No	Patent Status	No. Diabetics <sup>1</sup>
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 <sup>2,3</sup>	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 <sup>2,4</sup>	US 9,146,243	Granted	32,215,300
			<b>~368 million Total</b>

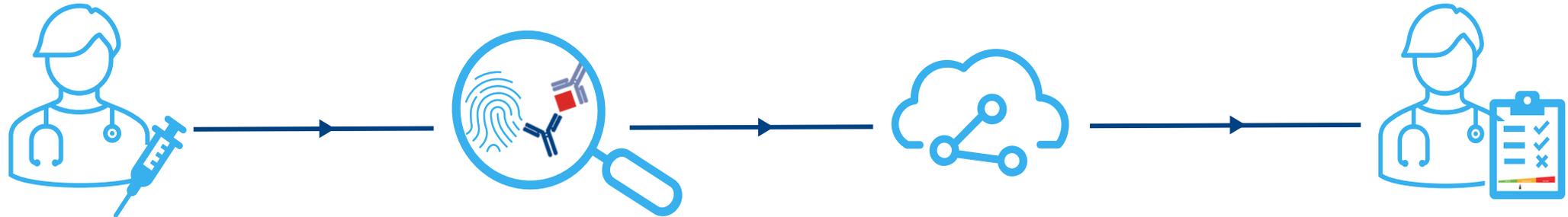


## Market assumptions

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

1. International Diabetes Federation (IDF) Atlas 10<sup>th</sup> 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



**Blood sample drawn**

**Biomarkers analysed**

**Results generated by PromarkerD Hub software**

**Results and intervention plan delivered**

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



ASX: PIQ

## How PromarkerD results are delivered



Prognostic **16%** indicates a **moderate** risk of decline in kidney function\*

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

\*as defined by incident diabetic kidney disease (eGFR <60ml/min/1.73m<sup>2</sup>) in the next four years. Note: if eGFR level at the time of the test is already <60ml/min/1.73m<sup>2</sup>, then the risk of a further decline in kidney function is defined as an eGFR decline >30% in the next four years

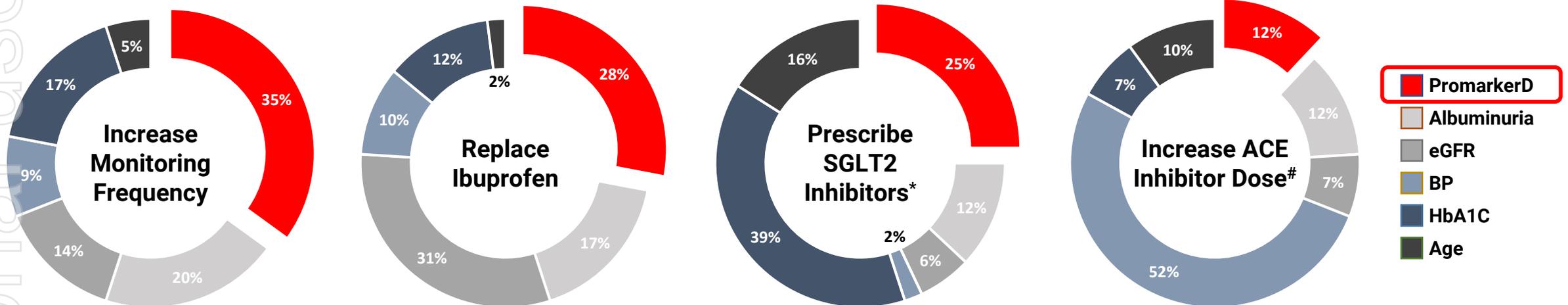


# PromarkerD: Clinical Utility & Decision Impact

Launch strategy supported by engagement with KOLs and primary care physicians

## Published Research<sup>1</sup> indicates physicians would use PromarkerD to inform patient treatment decisions

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



\* SGLT2-inhibitor class of medications are already widely used for the treatment of diabetes, and now also indicated for cardiovascular disease and DKD.

# ACE Inhibitor class of medications are commonly used for the treatment of high blood pressure and heart failure.

1. PLOS ONE. 2022

# PromarkerD: Precision in the Clinic



ASX: PIQ



## Peer Reviewed

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

**10+ Peer Reviewed Publications**

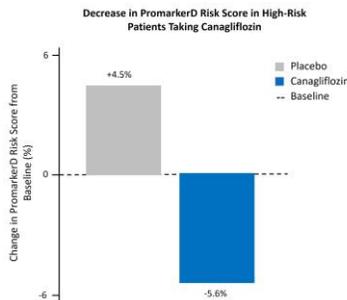
### World leading results:

- 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)

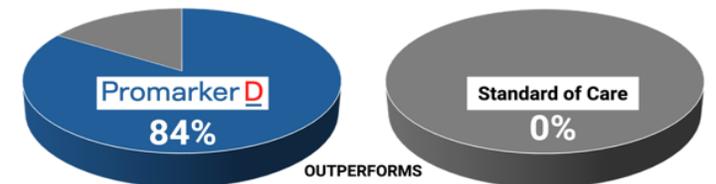
- **96% of physicians** were likely to use PromarkerD test scores for clinical decision making
- PromarkerD consistently ranked as **one of the top 2 factors** driving physician decision-making:
  - monitoring frequency
  - use of anti-inflammatories
  - prescribing SGLT2s
  - ACE inhibitor dosing

[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: Precision Medicine



ASX: PIQ

## 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



ASX: PIQ

## Prognostic Validation for Type 1 Diabetes

Davis TME, et al. Application of a validated prognostic protein biomarker test for renal decline in type 2 diabetes to type 1 diabetes: The Fremantle Diabetes Study Phase II. *ADC* [2024](#).

## 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](#).

## Prognostic Validation

Peters KE, et al. Validation of a Protein Biomarker Test for Predicting Renal Decline in Type 2 Diabetes: The Fremantle Diabetes Study Phase II. *J Diab Comp*. [2019](#).

## Prognostic Development

Peters KE, et al. Identification of Novel Circulating Biomarkers Predicting Rapid Decline in Renal Function in Type 2 Diabetes: The Fremantle Diabetes Study Phase II. *Diabetes Care*. [2017](#).

## Diagnostic Study

Bringans SD, et al. Comprehensive Mass Spectrometry Based Biomarker Discovery and Validation Platform as Applied to Diabetic Kidney Disease. *EuPA Open Proteomics*. [2017](#).

## Cross-platform Validation

Bringans SD, et al. The New and the Old: Platform Cross-Validation of Immunoaffinity MASS Spectrometry versus ELISA for PromarkerD, a Predictive Test for Diabetic Kidney Disease. *Proteomes*. [2020](#).