



**Proteomics International**

LABORATORIES LTD

**ASX Release**

**19 September 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 attendees at the Pitt Street Research Life Sciences Conference, Sydney on 19 September 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](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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ASX: PIQ

# Proteomics International

LABORATORIES LTD

## Pitt Street Research Life Sciences Conference

### *Investor Presentation*

19 September 2024

**Dr. Richard Lipscombe**

Managing Director

# Disclaimer

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

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# Proteomics International Laboratories Ltd



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

Three key focus tests driven by a proprietary platform technology:

PromarkerD

*Diabetic Kidney Disease*

COMMERCIALISATION

- In commercialisation 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

PromarkerEndo

*Endometriosis*

DEVELOPMENT

COMMERCIALISATION

- Test in late-stage development 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

PromarkerEso

*Esophageal Cancer*

DEVELOPMENT

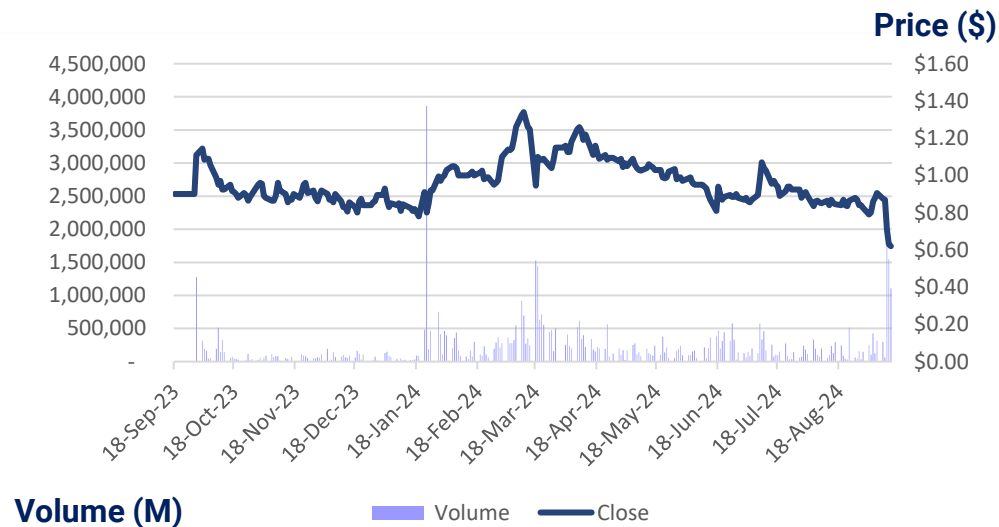
COMMERCIALISATION

- Test nearing commercialisation to diagnose Esophageal Cancer
- 1 in 20 cancer deaths worldwide due to esophageal cancer
- Test identified up to 90% of patients with the disease

# Corporate Overview

## Corporate Snapshot

ASX code	PIQ
Market Capitalisation	A\$78m
Cash (30 June 2024) (+ R&D Tax Incentive ~\$2m H1 FY25)	~A\$6.6m
Share Price (17 September 2024)	A\$0.60
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 53%
- 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
  - Recruiting to accelerate commercialisation of 3 lead tests
    - additional C-suite executives & Board renewal



# 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 \$



## 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 IVD (Europe); 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



## 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

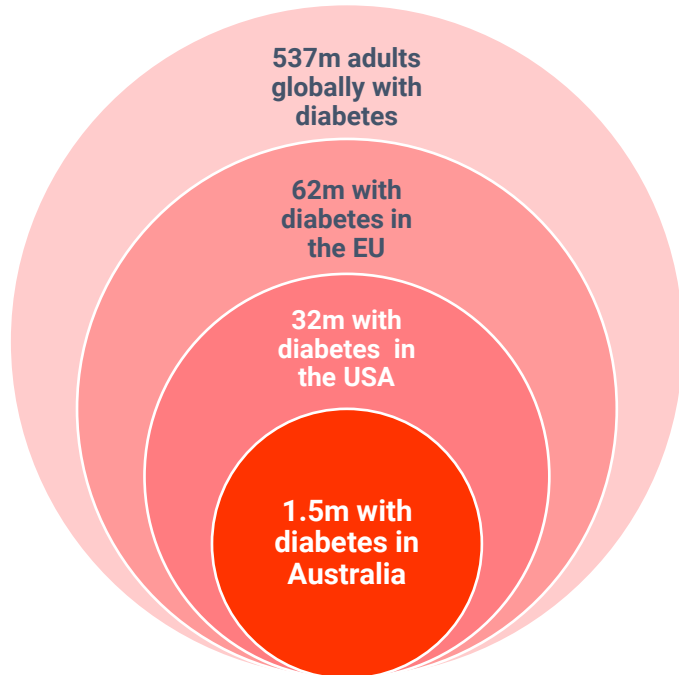


## Each test has whole of market appeal

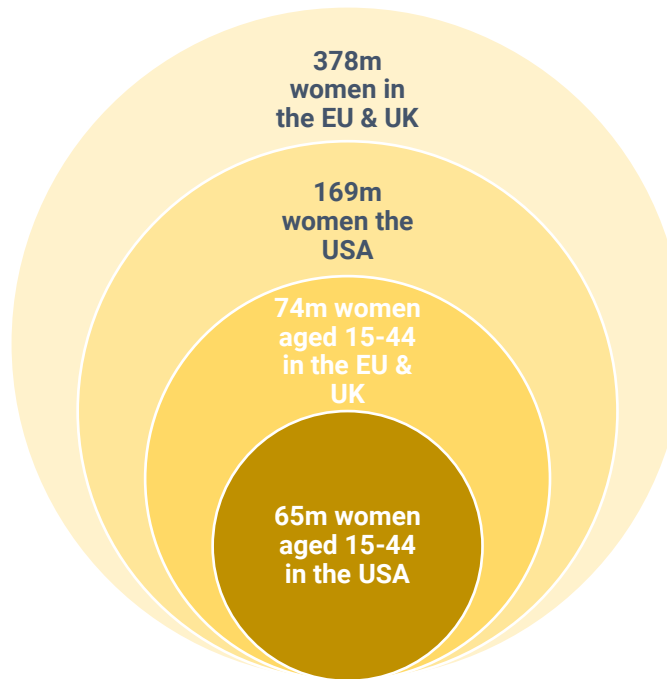
- Pharma
- Clinical pathology labs
- Diagnostic platform developers
- Physicians
- Patients

# The Problem: Target Populations for DKD, Endo and Eso

10.5% of global adult population have diabetes

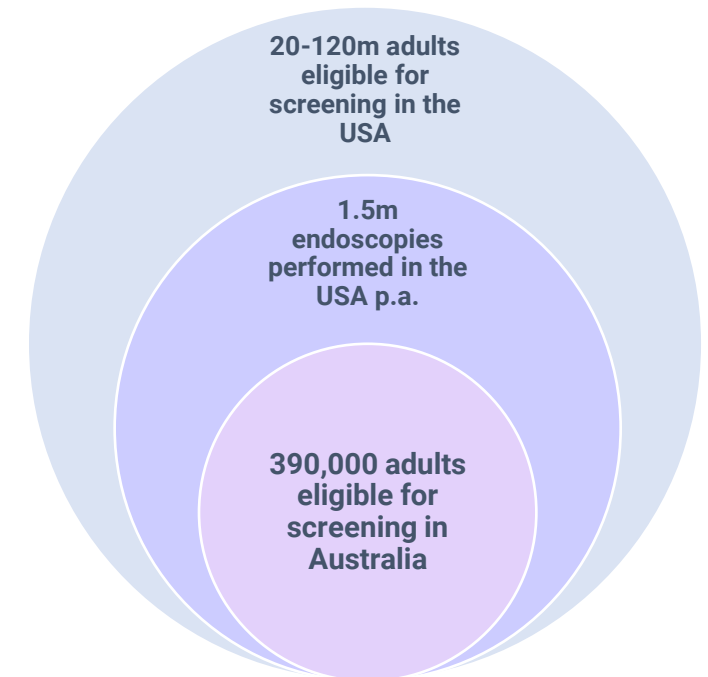


1 in 9 women have endometriosis



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

*(Diagnosed by endoscopy with biopsy)*



# The Solution: Precision Medicine Targeting Unmet Needs



## PromarkerD

### 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 therapeutics treatments available – GLP-1 agonists, gliflozin class (SGLT-2s)
- **Targeting Launch Q1 CY25**

## PromarkerEndo

### 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
- Novel blood test is ~90% accurate
- Significant community, Government and personal interest in the Endometriosis space
- **Targeting Launch Q2 CY25**

## PromarkerEso

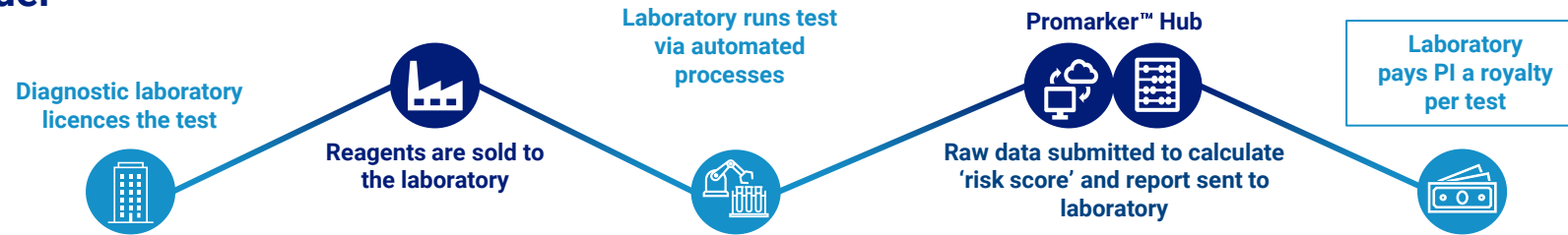
### Esophageal Cancer

- **1 in 20 cancer deaths worldwide due to esophageal cancer**
- **5 year survival rate < 20%**
- Novel blood test is ~90% accurate
- World-first blood test to screen for esophageal cancer
- Standard of care for diagnosis is endoscopy, which is costly and time consuming
- **Targeting Launch Q1 CY25**



# Go-to-Market Pathways

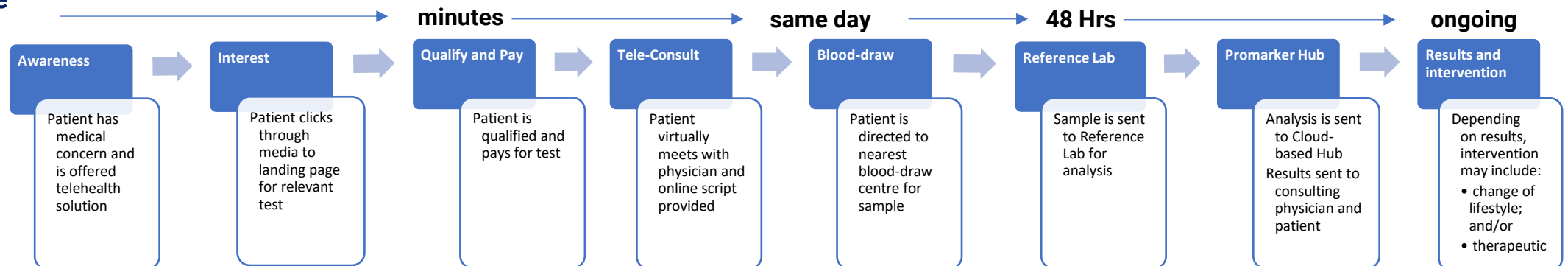
## Traditional licensing model



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









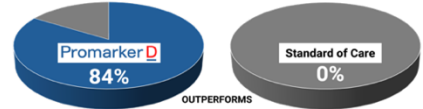






Significantly speeds up time to diagnoses, treatment & intervention



Key advantages: Move from weeks/months to hours for script & cost of patient acquisition < compared to traditional model

# PromarkerD Global Rollout – Key Highlights

<b>Intellectual Property</b>		Patents granted in all major jurisdictions - PromarkerD Patent family & Trademark covers <b>72%</b> of the world's diabetes patients
<b>Regulatory</b>		<b>CE Mark</b> (EU) registration received for the PromarkerD Immunoassay IVD US sales utilising the Lab Developed Test (LDT) pathway via CLIA certified laboratories 
<b>Manufacturing scale-up</b>		ISO 13485 certified EU manufacturer Simple technology platform (immunoassay) – easy to use and integrate into existing pathology lab processes
<b>Peer Reviewed</b>		PromarkerD tested on over <b>5,000 patients</b> 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
<b>Physician Support</b>		<b>Clinical utility demonstrated</b> - US based survey showed <b>96%</b> 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.
<b>Outperforms Standard of Care</b>		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 
<b>The Need</b>		<b>Economic Cost:</b> 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
<b>The Treatments</b>		<b>New renal protective therapies:</b> 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
<b>The Utility</b>		<b>Complementary diagnostic</b> - 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
<b>Breakthrough Study</b>		<b>PromarkerD validated for Type 1 (T1D) diabetes</b> - demonstrated <b>high accuracy</b> (AUC of 0.93) in predicting chronic kidney disease in patients with T1D (represents 10% of all diabetes cases); Offers a new target market

# Launch Strategy for DTP

**Establishing first sales via direct-to-patient (DTP) builds product awareness and drives mainstream use and subsequent volume**

**Rapidly establish each Promarker test as the key tool for patients & physicians**

## Step 1

### Engage patients

- Direct to consumer advertising
- Patient advocacy groups
- Nurse practitioners & physicians via KOLs

## Step 2

### Motivate patients

- Understand their risk of disease
- Ease of access
- Telehealth consult for diagnosis

## Step 3

### Provide patient access

- Reduce barriers to obtaining a test
- Provide immediate fulfillment

## Step 4

### Drive and Grow sales

- Builds market awareness
- Focus on highly motivated patients groups (e.g. T1D and endometriosis)
- Create a buzz about the tests
- Option to expand to new regions and partners

**Initial use via self-pay**

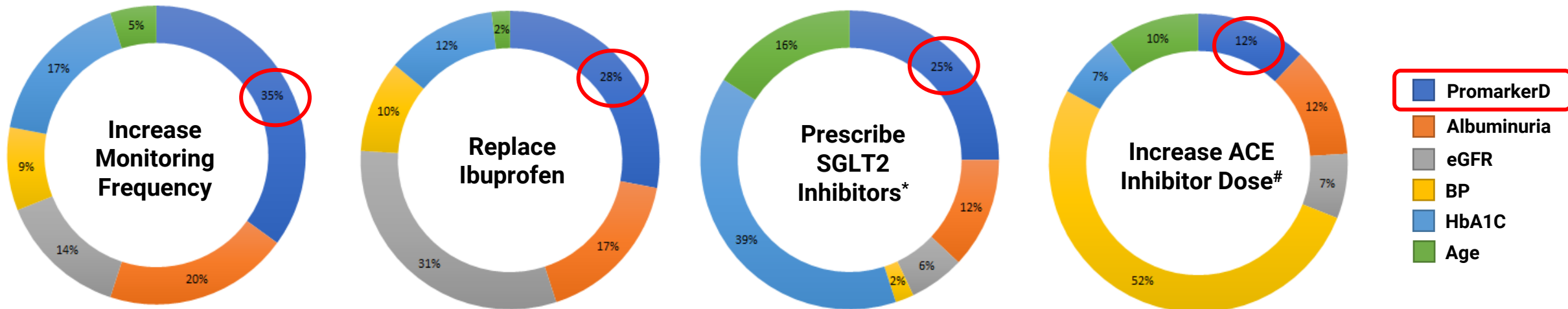
**Existing PromarkerD PLA code pricing provides engagement point for insurers  
Usage builds case for reimbursement of PromarkerEndo and PromarkerEso**

# PromarkerD: Clinical Utility & Decision Impact

Launch strategy supported by engagement with KOLs and primary care physicians

Research 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.

# 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

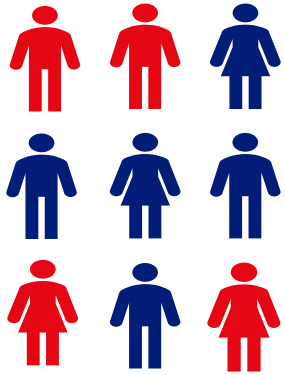
- Securing public reimbursement (Puerto Rico linked to CMS pricing and established PLA code)
- Expanding uptake of the test through engagement with primary care physicians
- *Exploring additional sales to neighbouring territories*



# 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

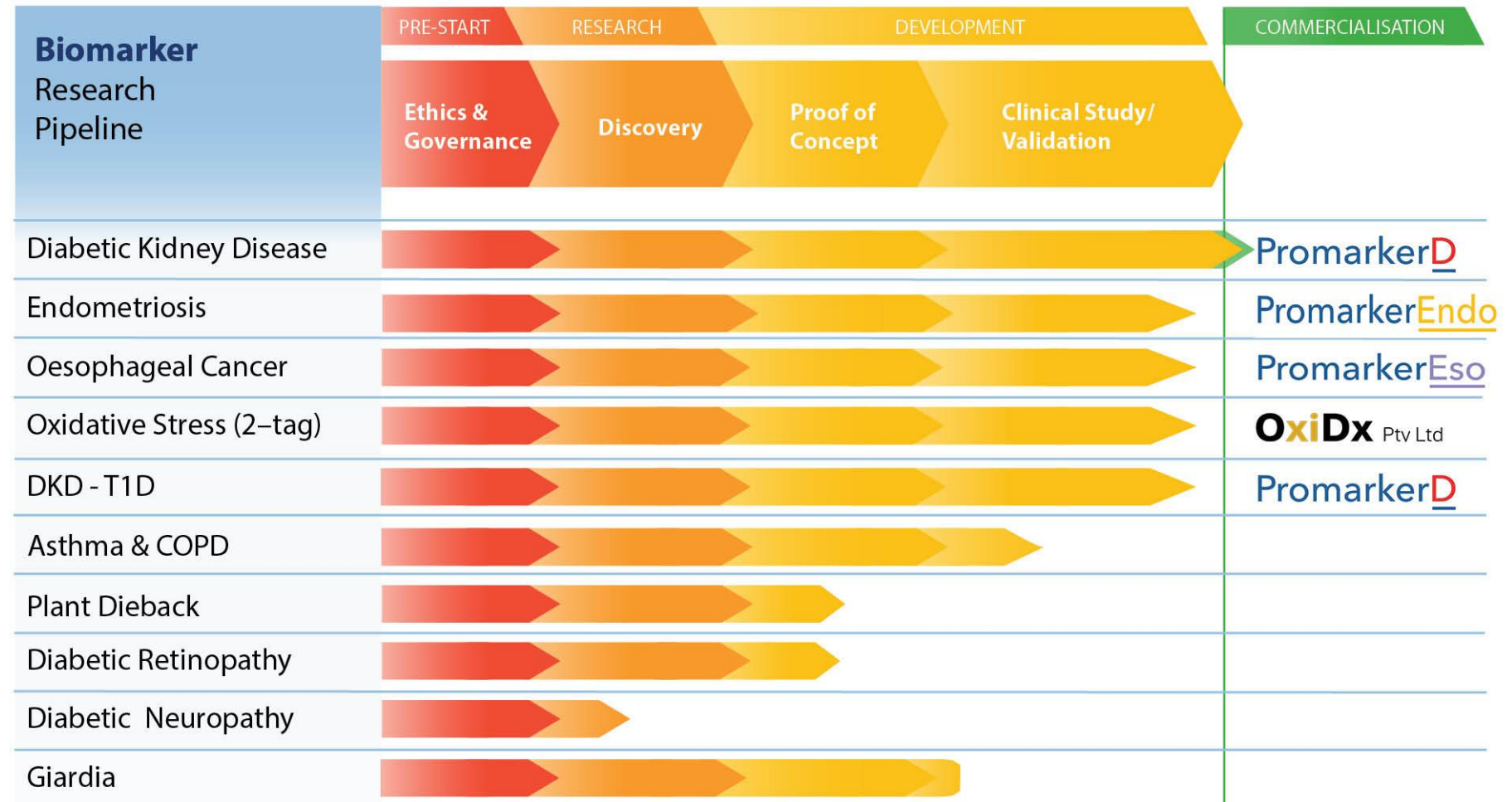
# Pipeline of Precision Diagnostics

## Platform technology drives deep pipeline of novel diagnostic tests

### 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



# PromarkerEndo: Endometriosis

## World-first blood test 'Promarker<sup>Endo</sup>' in late-stage development

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' nearing 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

- **Prototype test identified up to 90% of patients with the disease**  
(World Congress Esophageal Diseases, Sept '23)
- **Patents granted in Europe, China, Australia; USA pending**
- Model optimisation refined using 'traffic light' system to improve test performance for clinical use
- **Presenting latest results 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:
  - ❑ 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

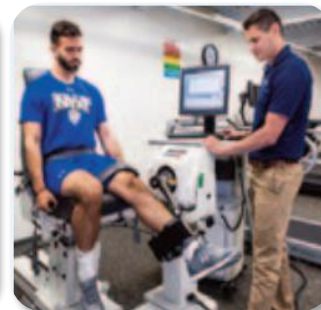
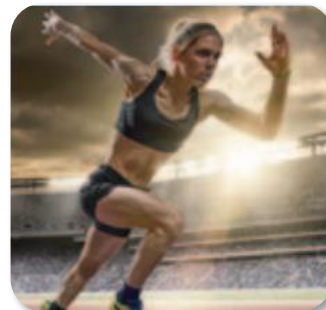
**OxiDx**

### 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





# 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 commercial readiness
- 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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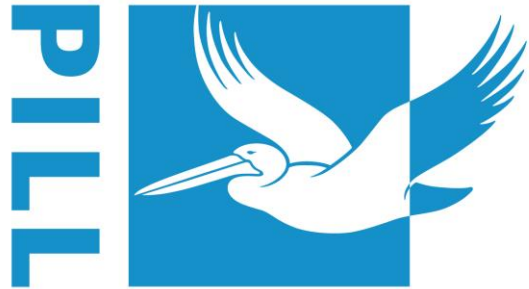
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# **Proteomics International**

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# 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 James William** PhD (Melbourne), MBA (UWA), BSc, Hons (Aberdeen), GAICD, Non-Executive Deputy Chair

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.

# 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



**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)



**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



**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



# 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

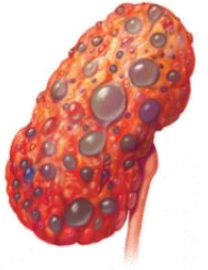


## Solution



## 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



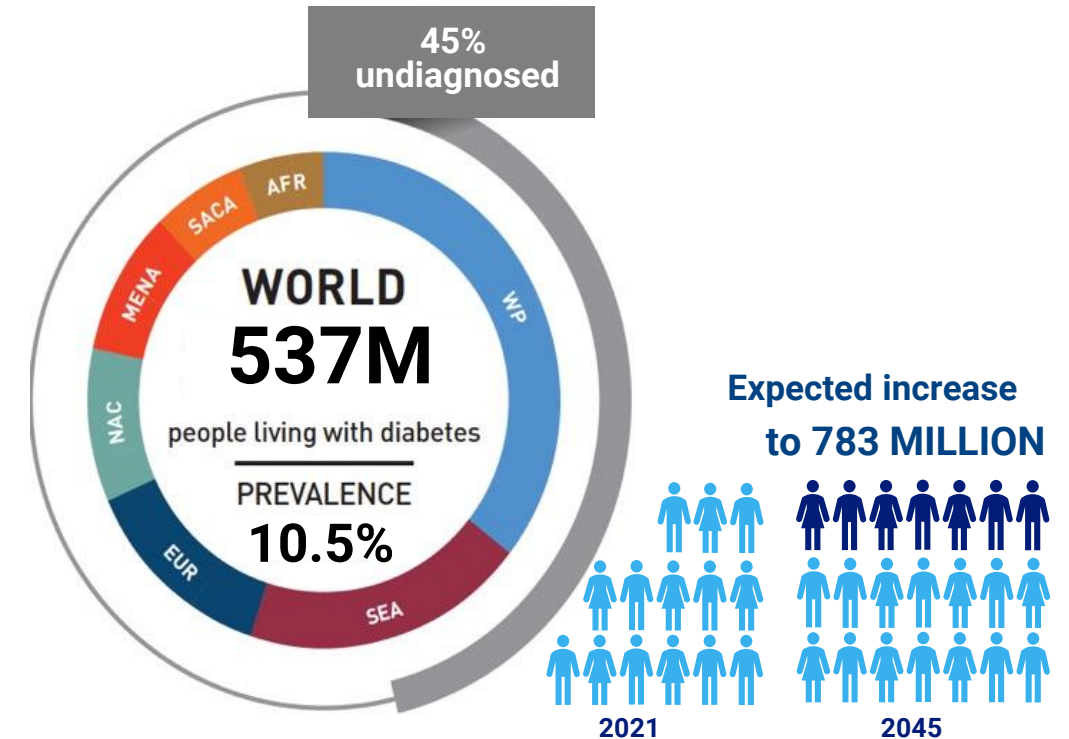
Healthy Kidney

# PromarkerD - Patented in all Major Markets

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
			~368 million Total

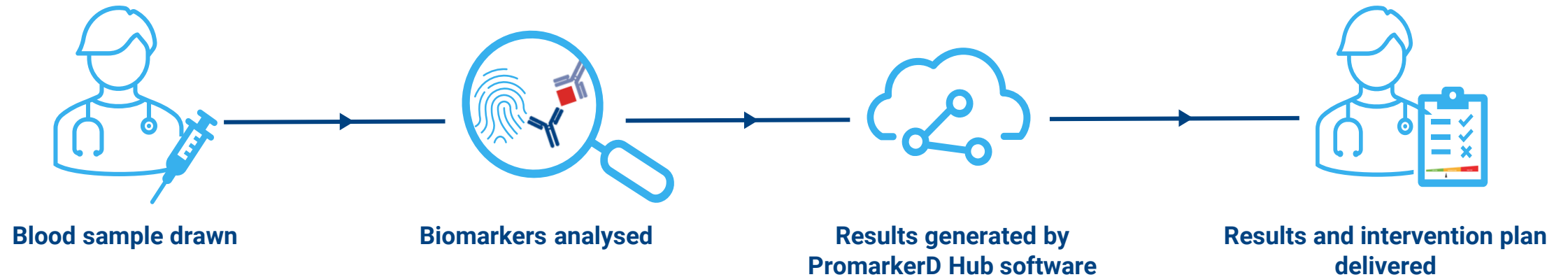


## Market assumptions

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

1. International Diabetes Federation (IDF) Atlas 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



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

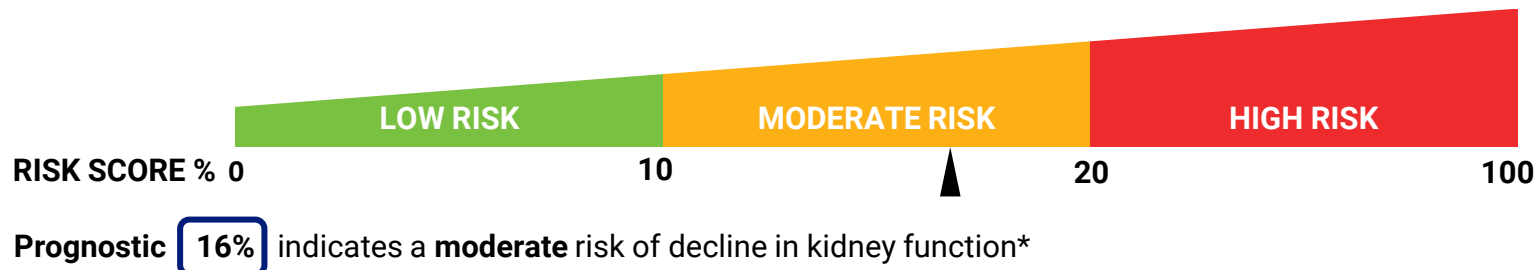
Clinician delivers results to patient

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"><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 in the Clinic




ASX: PIQ



## Peer Reviewed

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

10+ Peer Reviewed Publications

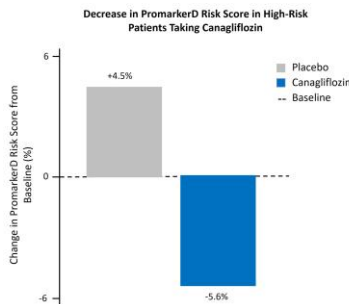
World leading results: 

- 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)

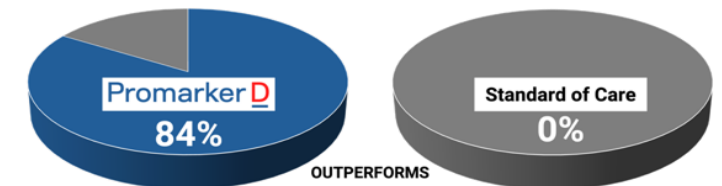
- 96% of physicians** were likely to use PromarkerD test scores for clinical decision making
- PromarkerD consistently ranked as **one of the top 2 factors** driving physician decision-making:
  - monitoring frequency
  - use of anti-inflammatories
  - prescribing SGLT2s
  - ACE inhibitor dosing

[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-1 ag
- 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](#).