



**Proteomics International**

LABORATORIES LTD

**ASX Release**

**25 July 2023**

**ASX code: PIQ**

## **Proteomics presents at 17<sup>th</sup> Bioshares Biotech Summit**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) is pleased to release a copy of the presentation to be provided by Dr Richard Lipscombe to delegates at the 17<sup>th</sup> Bioshares Biotech Summit on 25 July 2023.

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

ENDS

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# Proteomics International

LABORATORIES LTD

## 17<sup>th</sup> Bioshares Biotech Summit

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24-25 July 2023

**Dr. Richard Lipscombe**  
Managing Director

# Disclaimer



ASX: PIQ

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# Proteomics International Laboratories Ltd



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

## Diagnostics (Dx)

### PromarkerD

- Predictive test for early identification of diabetic kidney disease (DKD)
- In market, cost-effective, easy to use, patented technology
- Licensed to Sonic Healthcare USA for use in the world's primary healthcare market

### Promarker™ Pipeline

Strong pipeline of novel blood tests in development – Endometriosis, Asthma & COPD, Oesophageal cancer, Diabetic retinopathy, Oxidative Stress and more

## Bioanalytical Services

- Growing demand from industry for specialised analytics
  - Thriving sectors of pharmacokinetic (PK) testing and biosimilars
- State-of-the-art accredited (ISO 17025 and ISO 13485) cutting-edge facility
- Revenue partially offsets the cash burn from R&D and product development

## Financial & Corporate

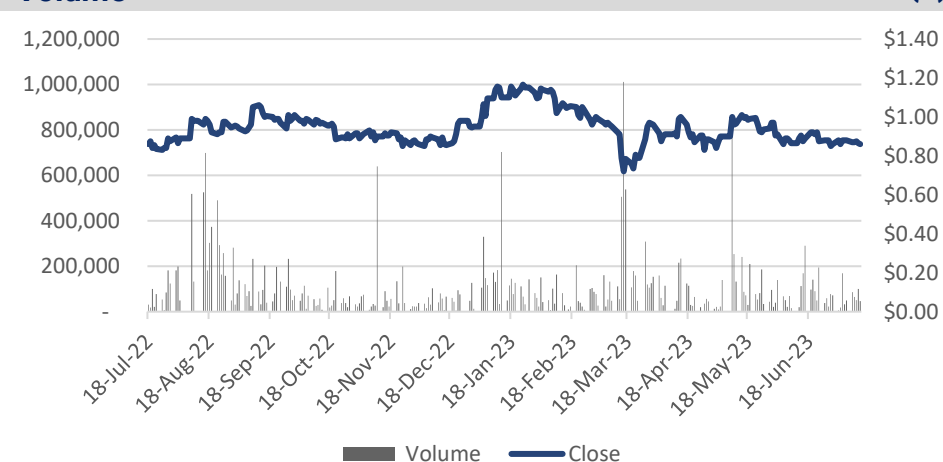
- ASX listed; 34 staff; headquartered on QEII Medical Campus, Perth, WA
- Strong cash position to be strengthened by R&D Rebate (~\$1.8m) and upcoming options conversion (1.25m @ \$0.50 – Aug 23)
- Expansion strategies implemented to accelerate growth
- OxiDx P/L spun-out to commercialise oxidative stress IP & technology
- Dynamic M&A activity in precision medicine, diagnostics and CRO (clinical trials) sectors

## Corporate Snapshot – 17/7/2023

ASX code	PIQ
Share Price	A\$0.875
Shares on issue (+2.5m options)	121m
Market Capitalisation	A\$104m
Revenue & other income – FY22	A\$3.4m
Cash (30 Jun '23 + ~\$1.8m R&D tax incentive due Q4 CY23)	\$6.0m
Average Quarterly cash burn – FY23	A\$1.4m
Directors Shareholding	18%

### Volume

### Price (\$)



# Promarker D

PROACTIVELY CHANGING RENAL HEALTHCARE

*A simple blood test for predicting diabetic kidney disease*



# Problem and Solution – Diabetic Kidney Disease



## The Problem

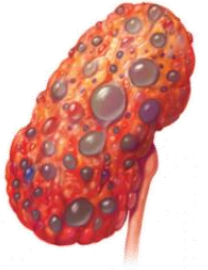
- **537 million adults** with diabetes globally
- **1-in-3** with diabetes have chronic kidney disease
- **Kidney disease is a silent killer** - kidney function can **fall below 15-20% with no symptoms**
- Damage to kidneys is **irreversible**, therefore **early detection** is paramount
- Diabetic kidney 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



## 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

### PromarkerD

- 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: Predicting Diabetic Kidney Disease

## What is PromarkerD?

- First-in-class, cost-effective test that predicts the risk of Diabetic Kidney Disease (DKD) in patients with type 2 diabetes (T2D)
- A simple blood test that measures three plasma protein biomarkers combined with three simple clinical factors
- Predicted 86% of otherwise 'healthy patients' who went on to develop diabetic kidney disease within 4 years

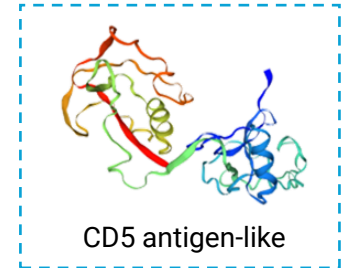
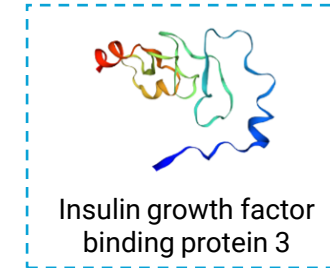
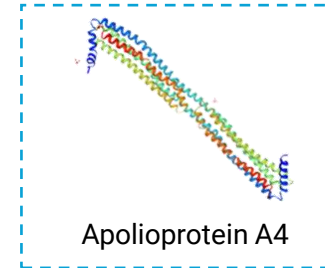


PromarkerD

**Prevention is better than  
cure**

- Invented by Proteomics International scientists in collaboration with the University of Western Australia
- Validated in collaboration with Janssen Research & Development (Johnson & Johnson)
- Manufactured to ISO 13485 standard in Europe

## Plasma Biomarkers



**Clinical factors: age, cholesterol, eGFR**

## Simple Immunoassay Platform



**Cost Effective /  
High-margin**

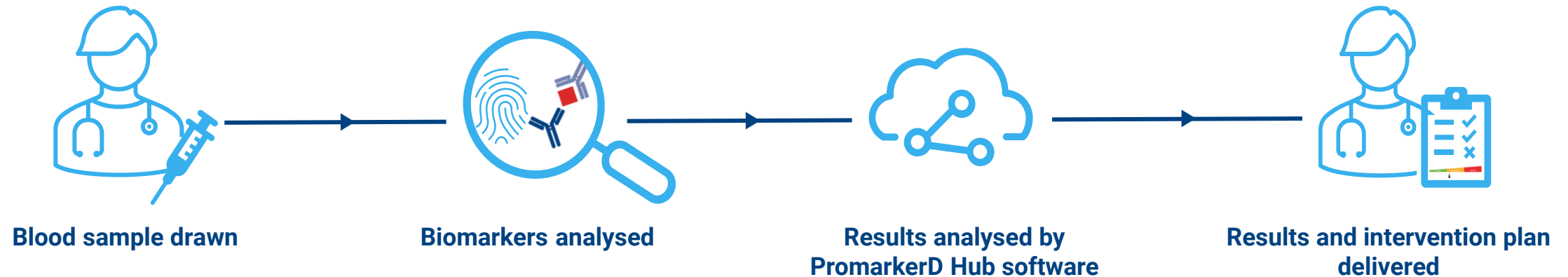
**Fast results:  
1.5 hr per assay**



CE Mark for PromarkerD ELISA as an IVD medical device (2020)

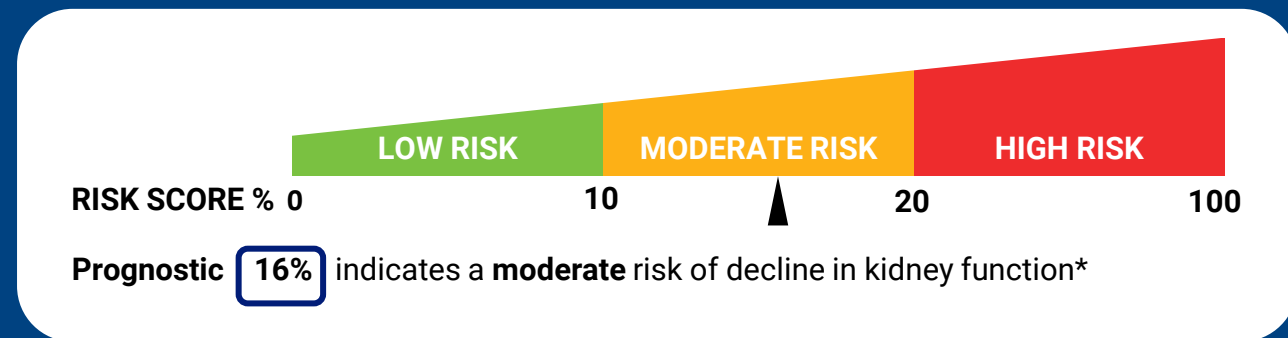
# PromarkerD: Enhancing Precision Healthcare

## Simple integration & utilisation



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

## How PromarkerD results are delivered



\*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



## Peer Reviewed

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

### 10+ Peer Reviewed Publications

World leading results: 

- Global clinical study N=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 ( $P = 1.3 \times 10^{-104}$ )

[Journal of Clinical Medicine (2020)]



## 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
- **PromarkerD outweighs the standard of care** (eGFR & ACR) for diagnosing kidney disease

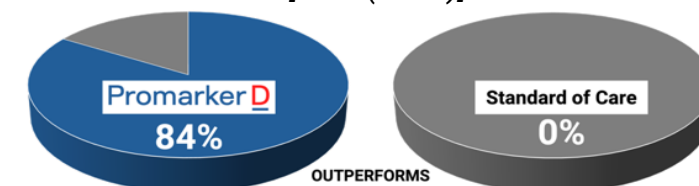
[AMCP Nexus (2021)]



## Outperforms Standard of Care

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

- N=857 community based patients
- 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)]



# New Treatment Option Identified to Slow DKD

The gliflozin class of type 2 diabetes drugs (SGLT2-inhibitors) grossed approximately US\$7bn of sales in 2020

*PromarkerD has the potential to become a new standard of care and change clinical practice*





**Janssen collaboration** assessed effect of SGLT2-inhibitor (gliflozin) vs placebo on PromarkerD risk scores

- **Aim:** Do 'at-risk' patients continue to decline, stabilize or recover?
- **Method:** Retrospective analysis of 2,008 patients from the CANVAS 4 year clinical trial:
- **Results:** Patients predicted at baseline by PromarkerD to be **high-risk** for developing DKD:
  - Treated with SGLT2i had **significantly lower scores** at Year 3 ( $\Delta$  score: -5.6%;  $p < 0.001$ )
  - Patients on **placebo remained high** ( $\Delta$  score: 4.5%;  $p = 0.035$ ) (Time\*TRT  $p = 0.002$ )
- **Conclusion:** SGLT2-inhibitors offer a potential treatment that can improve PromarkerD renal risk profile

J. Clin. Med. 2023, 12, 3247. <https://doi.org/10.3390/jcm12093247>

Article

## Canagliflozin Attenuates PromarkerD Diabetic Kidney Disease Risk Prediction Scores

Kirsten E. Peters <sup>1</sup>, Scott D. Bringans <sup>1</sup>, Ronan S. O'Neill <sup>1</sup>, Tasha S. C. Lumbantobing <sup>1</sup>, James K. C. Lui <sup>1</sup>, Timothy M. E. Davis <sup>2,\*</sup>, Michael K. Hansen <sup>3</sup> and Richard J. Lipscombe <sup>1</sup>

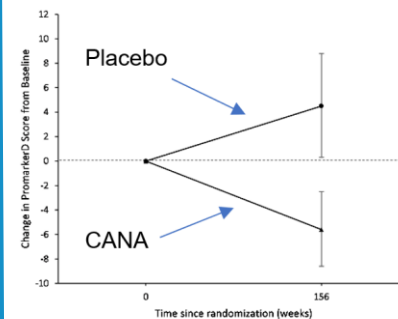
<sup>1</sup> Proteomics International, QEII Medical Centre, 6 Verdun Street, Nedlands, WA 6009, Australia

<sup>2</sup> Medical School, The University of Western Australia, Fremantle Hospital, Fremantle, WA 6959, Australia

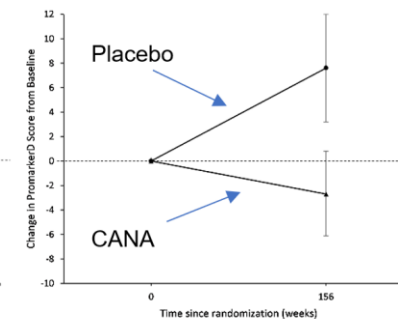
<sup>3</sup> Janssen Research and Development, LLC, Spring House, PA 19477, USA

\* Correspondence: [tim.davis@uwa.edu.au](mailto:tim.davis@uwa.edu.au); Tel.: +61-8-9431-3229; Fax: +61-8-9431-2977

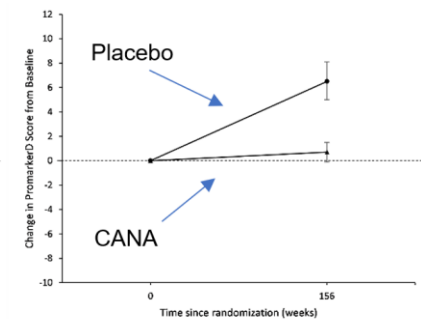
(This article belongs to the Special Issue [Editorial Board Member's Collection Series: Chronic Kidney Disease in Diabetes](#))



PromarkerD High Risk at Baseline



PromarkerD Med Risk at Baseline



PromarkerD Low Risk at Baseline

# PromarkerD: Key Publications



ASX: PIQ

<b>PromarkerD Demonstrates Benefit of Early Treatment with SGLT2-inhibitors</b>	Peters KE, et al. Canagliflozin Attenuates PromarkerD Diabetic Kidney Disease Risk Prediction Score. J Clinical Medicine. <a href="#">2023</a> .
<b>Clinical Utility</b>	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. <a href="#">2022</a> .
<b>PromarkerD vs Standard of Care</b>	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. <a href="#">2021</a> .
<b>Economic Health Benefit</b>	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. <a href="#">2021</a> .
<b>Global Multi-centre Validation</b>	Peters KE, et al. PromarkerD Predicts Renal Function Decline in Type 2 Diabetes in the Canagliflozin Cardiovascular Assessment Study (CANVAS). Journal of Clinical Medicine. <a href="#">2020</a> .
<b>Predicts Late-stage Renal Function Decline</b>	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. <a href="#">2022</a> .
<b>Prognostic Validation</b>	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. <a href="#">2019</a> .
<b>Prognostic Development</b>	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. <a href="#">2017</a> .
<b>Diagnostic Study</b>	Bringans SD, et al. Comprehensive Mass Spectrometry Based Biomarker Discovery and Validation Platform as Applied to Diabetic Kidney Disease. EuPA Open Proteomics. <a href="#">2017</a> .
<b>Cross-platform Validation</b>	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. <a href="#">2020</a> .
<b>Cross-over Validation</b>	Bringans SD, et al. A Robust Multiplex Immunoaffinity Mass Spectrometry Assay (PromarkerD) for Clinical Prediction of Diabetic Kidney Disease. Clin Proteomics. <a href="#">2020</a> .

# 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



**Dr David Kerr** MBChB, DM, FRCP, FRCP (Edin)  
– *United States*

Director of Research and Innovation, Sansum Diabetes  
Research Institute, Santa Barbara, California  
The digital health lead for the Diabetes Technology Society



**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



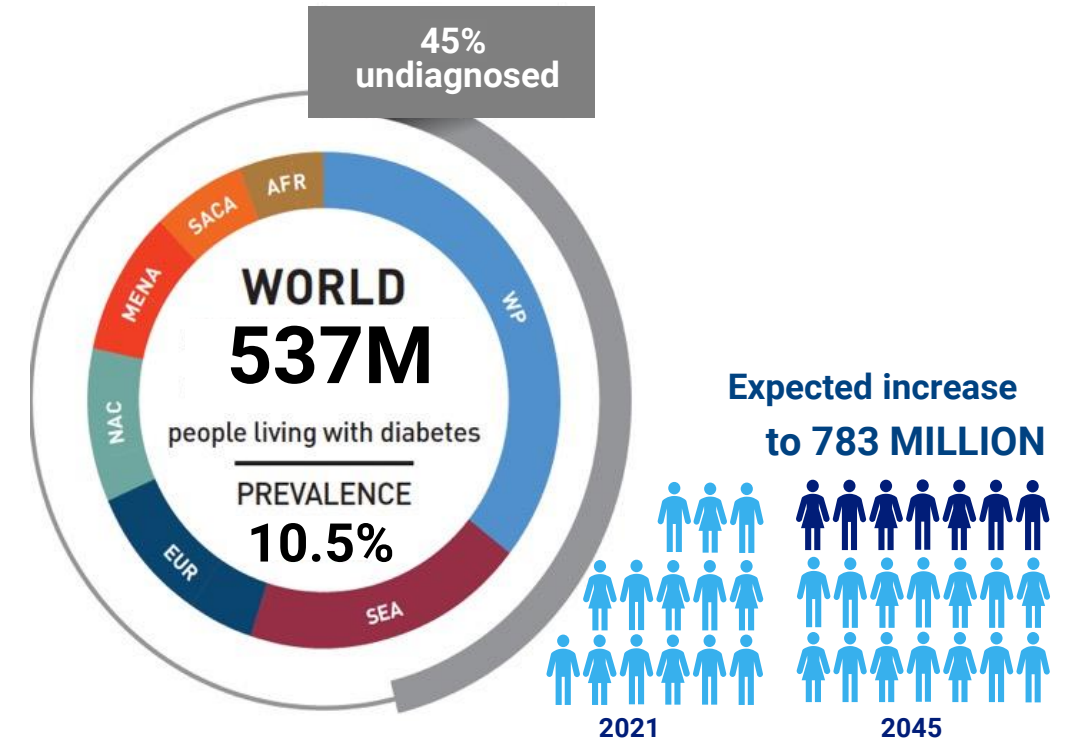
# PromarkerD Market Opportunity

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

## Diabetes incidence and Patent portfolio

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>

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)



## Market assumptions

- Patent family & Trademark covers 72% of world's diabetics<sup>1</sup>
- Test is performed **once per year per patient** on average
- Test **price minimum of US\$150** [based on stakeholder engagement responses in a market access study]
- Standard industry **royalty rates range from 5-15%**

# United States: Commercialisation in Progress

Proteomics International and Sonic Healthcare USA signed an exclusive licence agreement for the use and commercialisation of PromarkerD in the world's largest healthcare market (May 2023)



**SONIC HEALTHCARE  
USA**

**Over 7,000 Employees**

**Over 300 Sales reps**

**Over 400 pathologists**

**Services over 20 million patients**

**Targeting soft launch Q4 CY23**



**Marketing, Sample collection, Reporting**



**SONIC REFERENCE  
LABORATORY**

**PromarkerD Diabetic  
Kidney Disease Risk  
Assessment**

Early detection can significantly help prevent serious kidney damage.

**CLIA Certified Laboratories**

## US Reimbursement Pathway

Unique CPT  
Proprietary Laboratory  
Analysis (PLA) code  
approved

Centers for Medicare and  
Medicaid Services (CMS)  
posts updated code list  
PLA code (0385U) for  
PromarkerD effective

American Clinical Lab  
Association engaged by  
SHUSA to consider  
crosswalk or gapfill  
pricing

CMS Clinical Lab  
Fee Schedule  
(CLFS) Annual  
Meeting to consider  
pricing

CMS proposed  
pricing  
determinations  
published for  
comment

CMS final pricing  
published



Jan 2023



Apr 2023



May 2023



Jun 2023



Sept 2023



Jan 2024

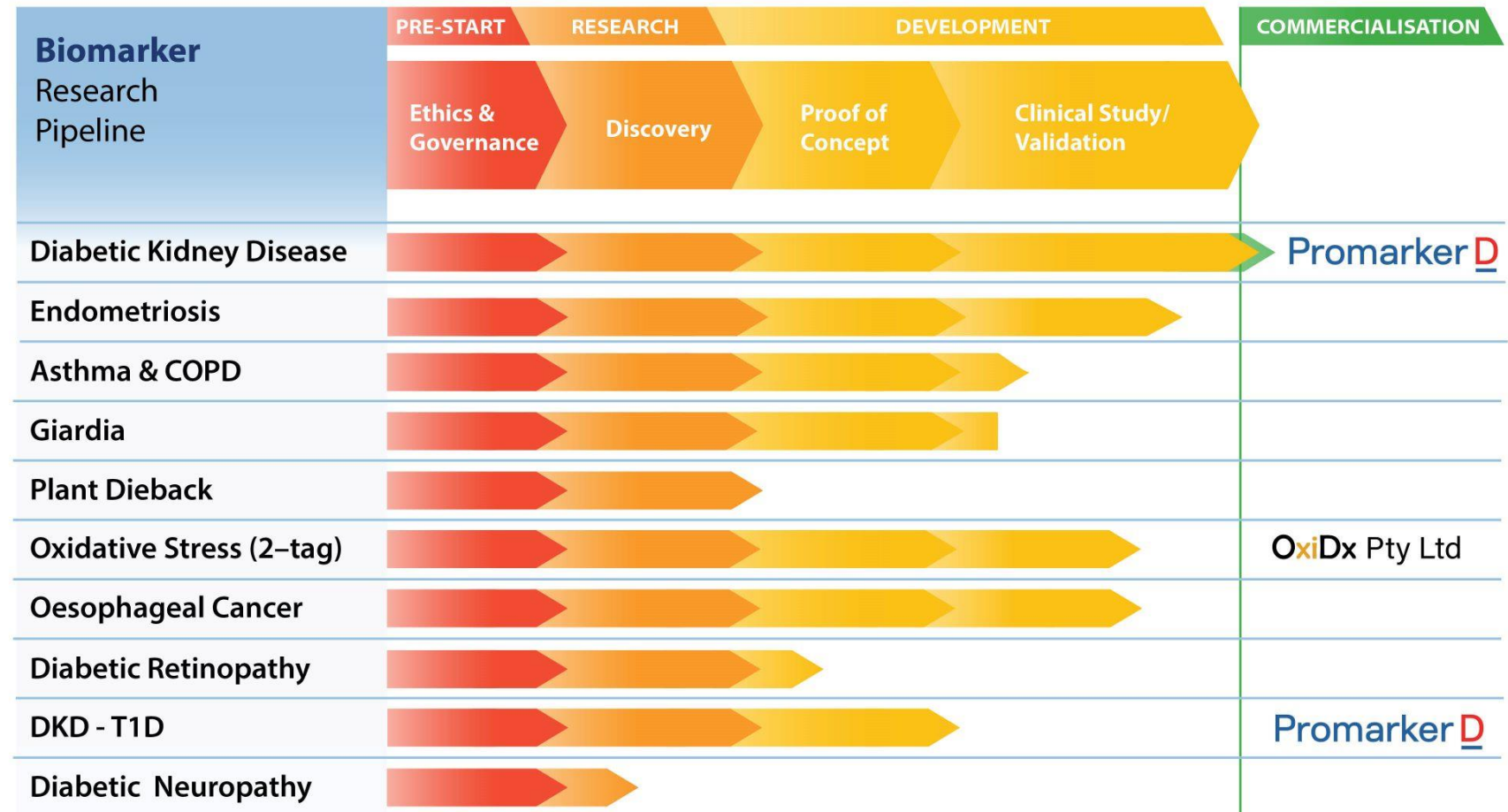
# Precision Diagnostics Pipeline

Deep pipeline of novel precision health and predictive diagnostic tests continues to expand

## Further global potential in new markets

- Employs the in-house Promarker™ technology platform to develop 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 & Oesophageal Cancer



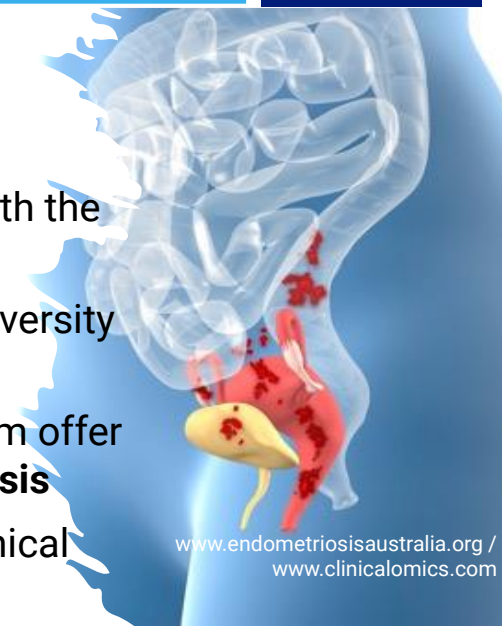
Proteomics International has two potential world-first blood tests in late-stage development

## 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
- Biomarkers identified via the Promarker™ platform offer a **potential world-first blood test for endometriosis**
- Next steps: confirm clinical performance and clinical utility in additional cohorts



## 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 esophagus (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 up to 90% of people with the disease (World Congress for Esophageal Diseases, Sept '22)
- Collaboration with QIMR Berghofer Medical Research Institute analysed 302 samples;
- Results indicate a **potential world-first blood test for oesophageal cancer**
- Latest results to be presented at the 19<sup>th</sup> World Congress for Esophageal Diseases (Toronto, Sept '23)

# Value Inflection Points

## 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	Sep	Dec	Mar	Jun	Impact
<b>PromarkerD</b>						
First Sales in USA						Initiate pathway to significant revenues
CMS Reimbursement Pricing Set						Supports broad adoption of test
Regulatory Submissions, Approvals & Reimbursement RoW						Build user confidence in product & assist in global roll-out
Licensing Deals in RoW						Drive global uptake and future revenue
<b>Promarker™</b>						
Endometriosis Dx						New first-in-class diagnostic test
Oesophageal Cancer Dx						New first-in-class diagnostic test
Diagnostics Pipeline Updates						New IP (validation & proof of concept results)
<b>Analytical Services</b>						
New Contracts						Engages potential future partners & enhances revenue profile

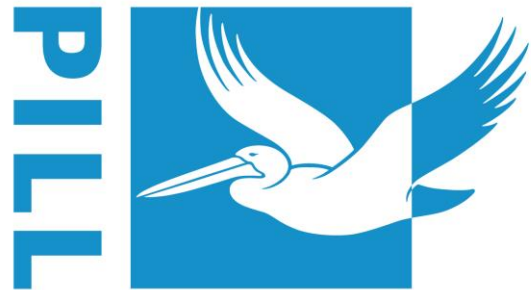
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# Board of Directors



## **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.



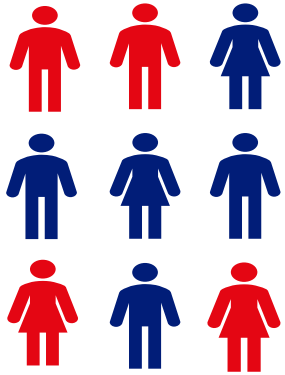
## **Dr Robyn Elliott** PhD Inorganic Chemistry (Monash), BSc(Hons) Chemistry (Monash), Non-Executive Director

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).

# 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

# PromarkerD: Commercialisation Underway

## Key highlights towards a global roll-out

Enormous Market	✓	537m adults have diabetes globally: 1-in-3 currently have diabetic kidney disease (DKD)
High Statistical Performance	✓	Peer reviewed publications – Clinical & analytical validity proven (Sensitivity 86%); PromarkerD significantly outperforms current standard of care
Big Pharma Collaboration	✓	 (J&J) – Global multi-centre clinical study - assessed PromarkerD against drug treatment
Therapeutic Treatments Available	✓	SGLT2-inhibitor class drug (canagliflozin) improves PromarkerD risk scores – potential as Complementary Diagnostic (CDx) [drug class already used for type 2 diabetes & now approved as new treatment for DKD]
Simple Technology Platform - PromarkerD Immunoassay	✓	Clinical pathology laboratories can easily introduce the PromarkerD immunoassay as an IVD kit or LDT
Regulatory Approvals	✓	CE Mark (Europe) registration received for the PromarkerD Immunoassay; US sales utilising the Lab Developed Test (LDT) pathway via CLIA certified laboratories; Secured ISO 13485 certification for the manufacture of medical devices
Regulatory Approvals - ongoing	●	Engaging with international partners and national regulators; application pending with Australian TGA
Manufacturing scale-up	✓	Technology transferred to ISO 13485 certified EU manufacturer; pilot batches of kit & assay completed
First Sales	✓	Sales initiated in Central America; Partnership with Sonic Healthcare USA announced for US mainland
Reimbursement	●	USA: Secured Unique PLA Reimbursement code & progressing toward payment coverage; Engaged with NHS (UK), 'NICE advice' published; Economic Health Benefit & Clinical Utility demonstrated

# Target Markets: Commercialisation in Progress



**United Kingdom**  
4.8m T2 diabetics

- **Licence with Apacor Ltd** for immunoassay test
- 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 are looked at by the broader healthcare industry and allow for positive engagement with private healthcare providers



**Puerto Rico & Dom Republic**  
1.3m T2 diabetics

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

## Next Steps

- Securing public reimbursement
- Expanding uptake of the test through engagement with primary care physicians
- Exploring additional usage in neighbouring territories



**Israel**  
0.6m T2 diabetics

- **Licence with Zotal Ltd** for immunoassay test
- Product registration on-hold pending first sales globally

## Next Steps

- Engaged with Zotal to initiate product registration and promote KOL awareness



**Rest of World**  
330m+ T2 diabetics

- Detailed market assessments completed

## Next Steps

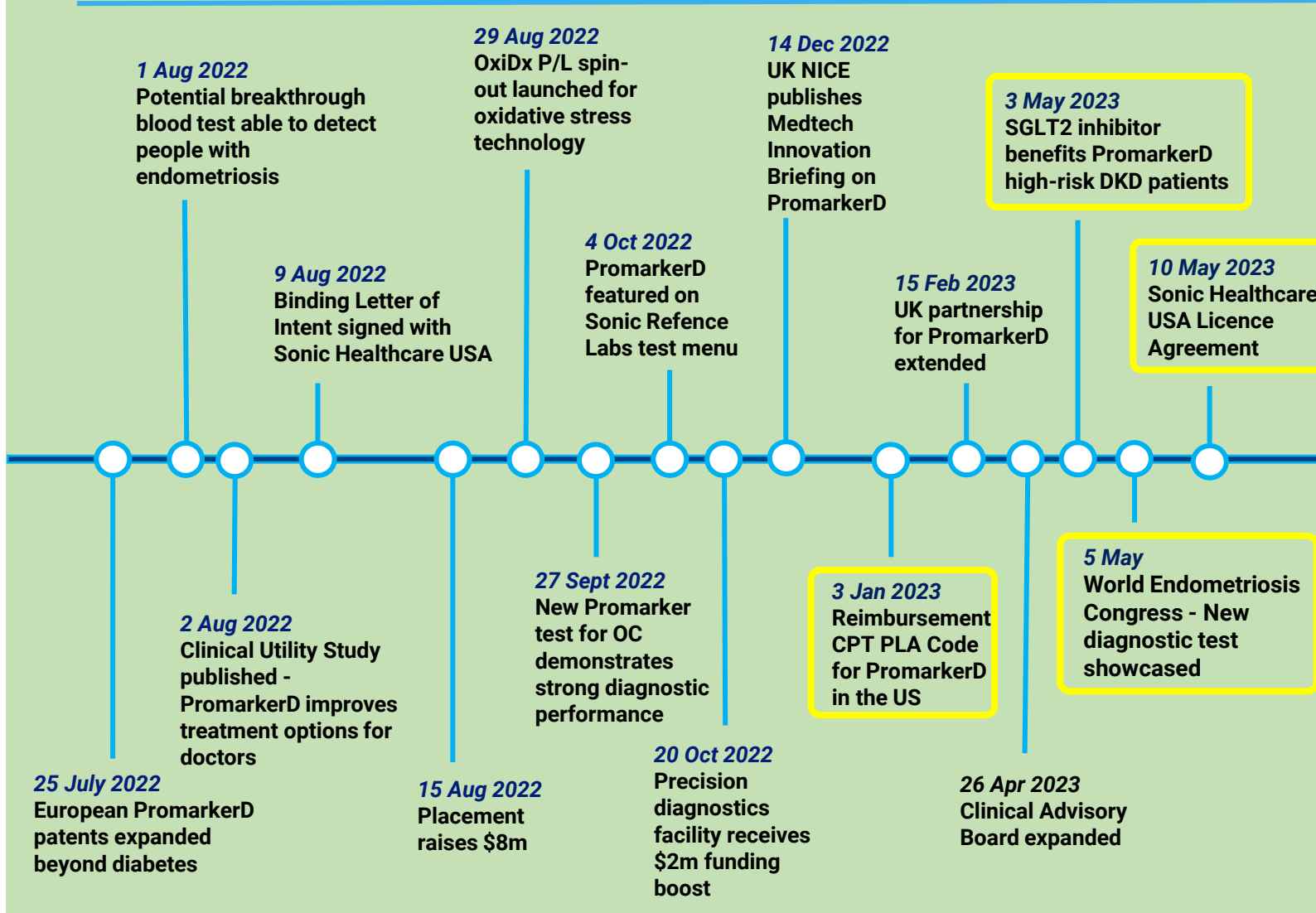
- Actively targeting potential partners in key jurisdictions

# Timeline & Milestones

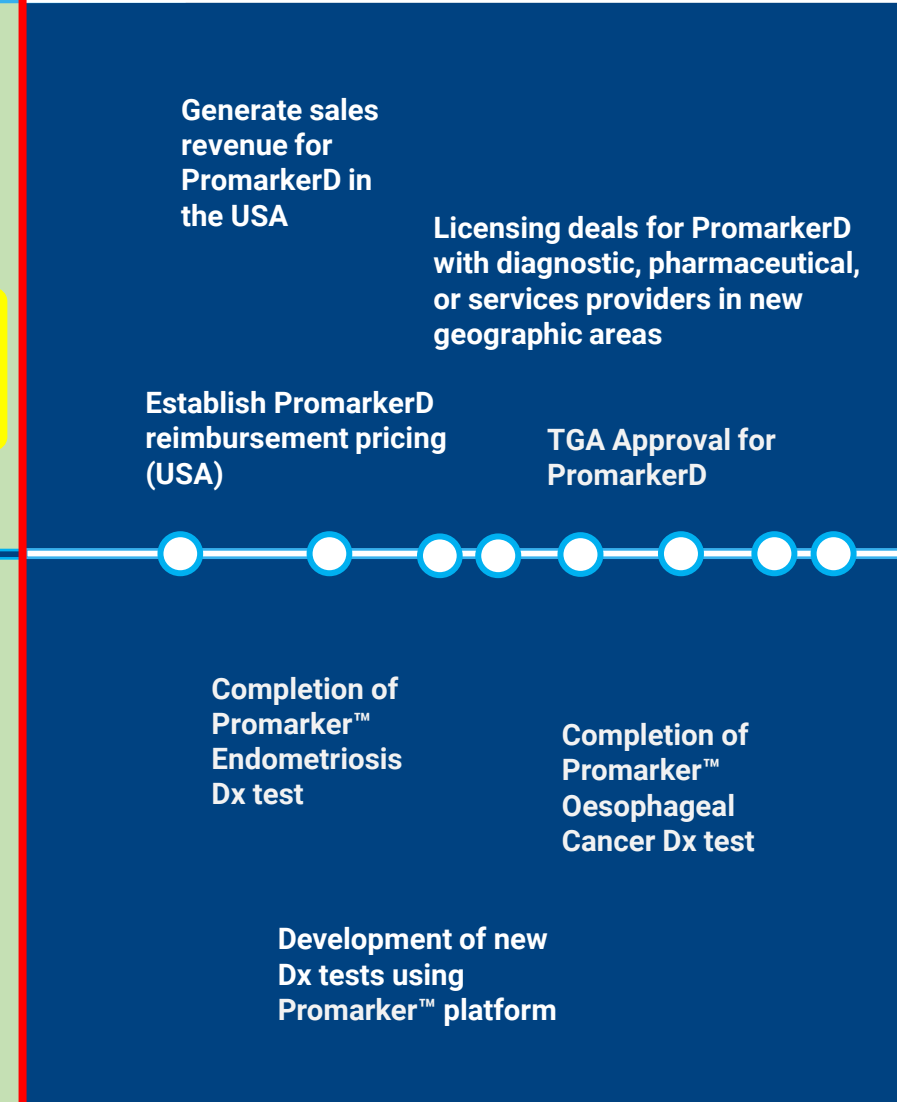


ASX: PIQ

## FY23 Achievements









## FY24 Targets & Milestones



# Peer Comparison



ASX: PIQ

		Stock Code	Company Focus	Market Capitalisation	Share Price	FY22 Revenue	FY22 Net Profit/Loss
	<b>Proteomics International Laboratories</b>	PIQ.ASX	Predictive blood test measuring novel protein biomarkers for DKD; simple, cost effective, commercial ready. Pipeline of novel diagnostic tests in development for chronic diseases.	<b>A\$106m</b>	A\$0.875	A\$1.7m	<b>(-A\$4.9m)</b>
	<b>Innoviq Ltd</b>	IIQ.ASX	Early stage in-licensed IP for various cancer diagnostics.	<b>A\$75m</b>	A\$0.81	A\$0.3m	<b>(-A\$18m)</b>
	<b>Lucid Diagnostics Inc</b>	LUCD.US	Cancer prevention medical diagnostics company with a DNA test (via LDT) for oesophageal cancer.	<b>A\$90m</b>	USD\$1.39	A\$0.6m	<b>(-A\$84m)</b>
	<b>Renalytix AI</b>	RENX.LSE RNLX.US	DKD test based on AI and predictive blood-based biomarkers, genetic factors and electronic health records. Expensive (US\$950 p/test), non-mass market.	<b>A\$232m</b>	GBP£1.27	A\$4m	<b>(-A\$78m)</b>
	<b>Rhythm Biosciences</b>	RHY.ASX	Pre-commercialisation proteomics derived diagnostic test for colon cancer licensed from CSIRO.	<b>A\$104m</b>	A\$0.47	Nil	<b>(-A\$8.8m)</b>
	<b>Clarity Pharmaceuticals</b>	CU6.ASX	Clinical stage radiopharmaceutical company focused on the diagnosis & treatment of serious disease.	<b>A\$228m</b>	\$0.875	Nil	<b>(-A\$24m)</b>

Source: Company filings. Market data as at 17 July 2023, exchange rates of GBP:AUD 1.92 and USD:AUD 1.47