



# Proteomics International

LABORATORIES LTD

## AGM Presentation

*2023 – a pivotal year*

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23 November 2023

**Dr. Richard Lipscombe**

Managing Director

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

Three key focus tests driven by a proprietary platform technology:

**PromarkerD**

Diabetic Kidney Disease

COMMERCIALISATION

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

**PromarkerEndo**

Endometriosis

DEVELOPMENT

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

**PromarkerEso**

Esophageal Cancer

DEVELOPMENT

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

## Corporate Snapshot (22/11/23)

|  |         |
|--|---------|
| ASX code   | PIQ     |
| Market Capitalisation  | A\$116m |
| Cash (30 Sept 23 + \$1.85m R&D tax incentive received Q4 CY23) | \$4.9m  |

|                                 |         |
|---------------------------------|---------|
| Share Price                     | A\$0.95 |
| Shares on issue (+1.4m options) | 122m    |

|                                    |          |
|------------------------------------|----------|
| Revenue & other income – FY23      | A\$3.3m  |
| Average Quarterly cash burn – FY23 | A\$1.55m |



## Financial and Corporate

- Top 40 Shareholders hold 49%
- Directors are highly aligned with shareholders holding 18%
- Multiple institutional & family office shareholders on the register
- State-of-the-art laboratories
  - Accredited (ISO 17025 and ISO 13485) cutting-edge facility
  - Specialist proteomics technology platform
  - Analytical services – pharmacokinetic (PK) testing & biosimilars
  - Headquartered on QEII Medical Campus, Perth, WA
- Revenue generating
  - Bioanalytical service business helps offset cash burn
  - Current revenue does not include any major sales of PromarkerD

# Board of Directors



ASX: PIQ



## **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.

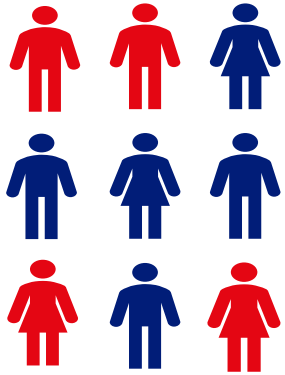


## **Dr Robyn Elliott** PhD Inorganic Chemistry (Monash), BSc(Hons) Chemistry (Monash), Non-Executive Director

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



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

# Promarker **D**

PROACTIVELY CHANGING RENAL HEALTHCARE

*A simple blood test for predicting diabetic kidney disease*



# Problem and Solution – Diabetic Kidney Disease



## The Problem

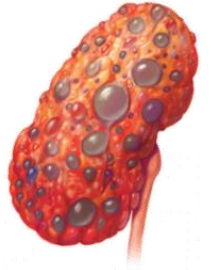
- **537 million adults** with diabetes globally
- **1-in-3** with diabetes have chronic kidney disease
- **Kidney disease is a silent killer** - kidney function can **fall below 15-20% with no symptoms**
- Damage to kidneys is **irreversible**, therefore **early detection** is paramount
- Diabetic kidney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



Roadblock

## Current standard-of-care diagnostics

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



Diseased Kidney



Solution

## 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: World Class Advisory Board



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

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

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



**Dr Ele Ferrannini MD** – *Italy*

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



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

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



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

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



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

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



**Dr Neil Skolnik MD** – *United States*

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



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

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



**Dr Alexander Turchin MD, MS** – *United States*

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

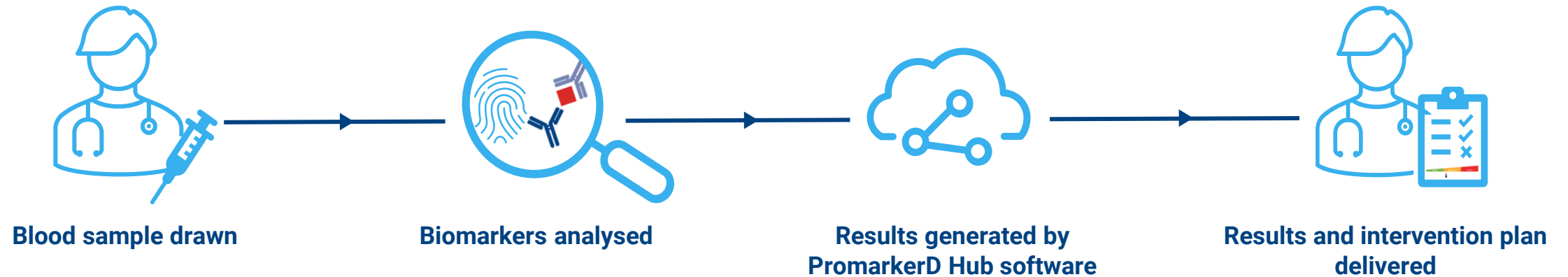


**Ms Hope Warshaw MMSc, RD, CDCES, BC-ADM, FADCES** – *United States*

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



# PromarkerD – 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



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## 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 in the Clinic




ASX: PIQ



## Peer Reviewed

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

**10+ Peer Reviewed Publications**

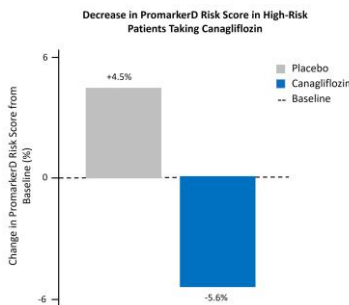
World leading results: 

- 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)**

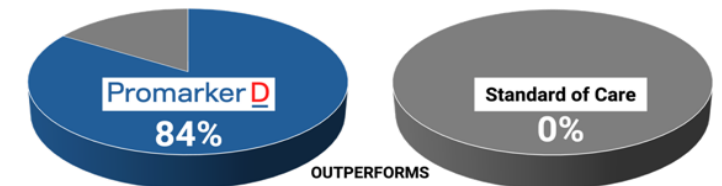
- **96% of physicians** were likely to use PromarkerD test scores for clinical decision making
- PromarkerD consistently ranked as **one of the top 2 factors** driving physician decision-making:
  - monitoring frequency
  - use of anti-inflammatories
  - prescribing SGLT2s
  - ACE inhibitor dosing

[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

### 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

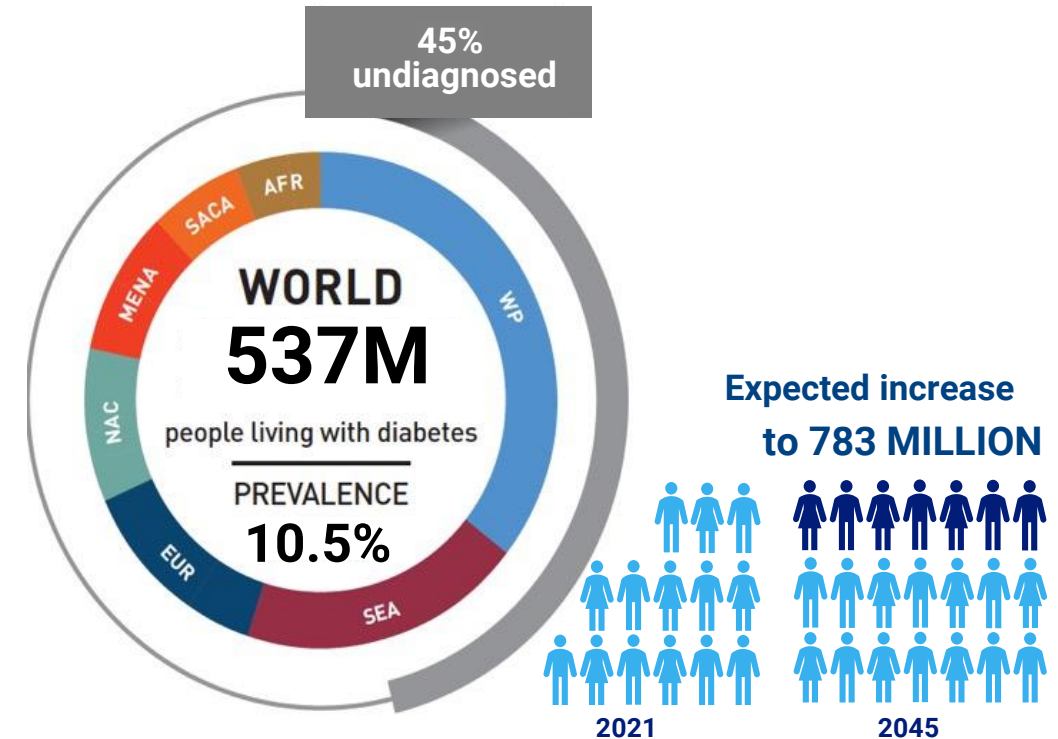
Actions taken **BEFORE** the onset of DKD

# PromarkerD - 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                    |
| <b>USA<sup>2,4</sup></b> | <b>US 9,146,243</b>   | <b>Granted</b> | <b>32,215,300</b>          |
|                          |                       |                | <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%**

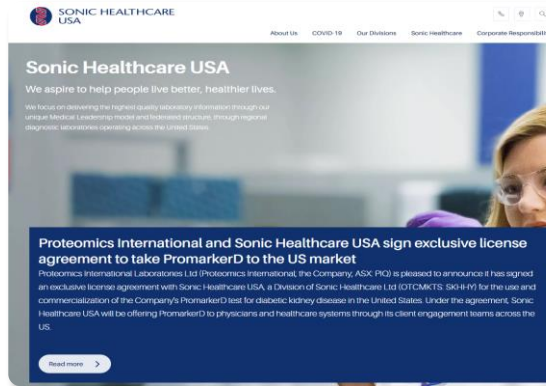
1. International Diabetes Federation (IDF) Atlas 10<sup>th</sup> Edition 2021 [Age group 20-79 years]  
 2. Australia, Europe, HK, USA patent family also covers testing for any form of kidney disease (Extra efficacy studies required)  
 3. Covers France, Germany, Italy, Spain, Turkey and the United Kingdom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

# United States: Commercialisation in Progress

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



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



**Marketing, Sample collection, Reporting**



**PromarkerD Diabetic  
Kidney Disease Risk  
Assessment**

Early detection can significantly help prevent serious kidney damage.

**CLIA Certified Laboratories**

Sonic is the third Largest laboratory medicine company in the US



Test listed on Sonic website & commercial launch expected in Q1 CY24

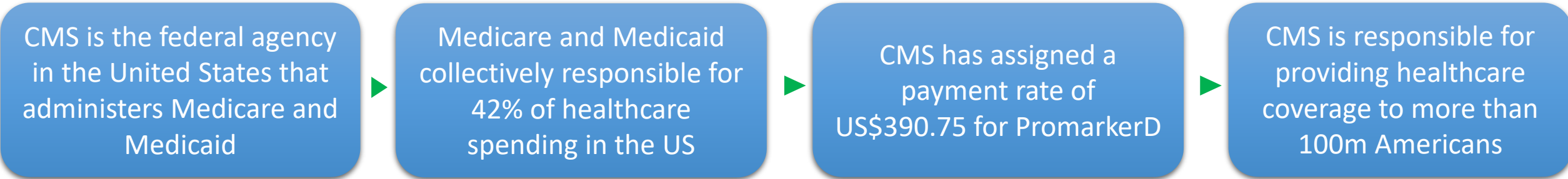


Sonic has labs spanning from Hawaii to Boston

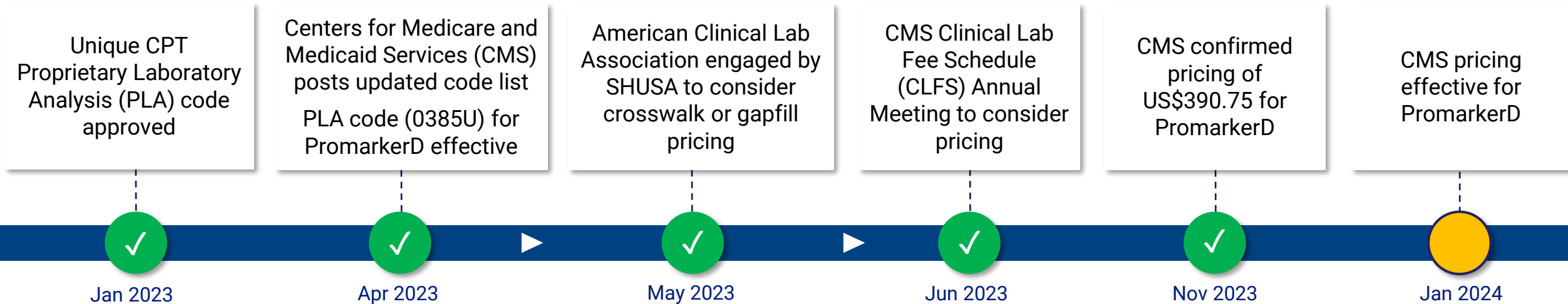


# Reimbursement in the US

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



## US Reimbursement Timeline





# Target Markets: PromarkerD

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



**United Kingdom**  
4.8m T2 diabetics

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

## Next Steps

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



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



**Germany, France, Spain**  
15.1m T2 diabetics

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

## Next Steps

- Actively targeting potential partners in key jurisdictions



**Rest of World**  
316m+ T2 diabetics

- Detailed market assessments completed; discussions ongoing

## Next Steps

- Actively targeting potential partners in key jurisdictions

# Pipeline of Precision Diagnostics

Platform technology drives deep pipeline of novel diagnostic tests

## Further global potential in new markets

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

## DIAGNOSTICS RESEARCH AND DEVELOPMENT – THE PROMARKER™ PIPELINE



# Dx Pipeline: Endometriosis

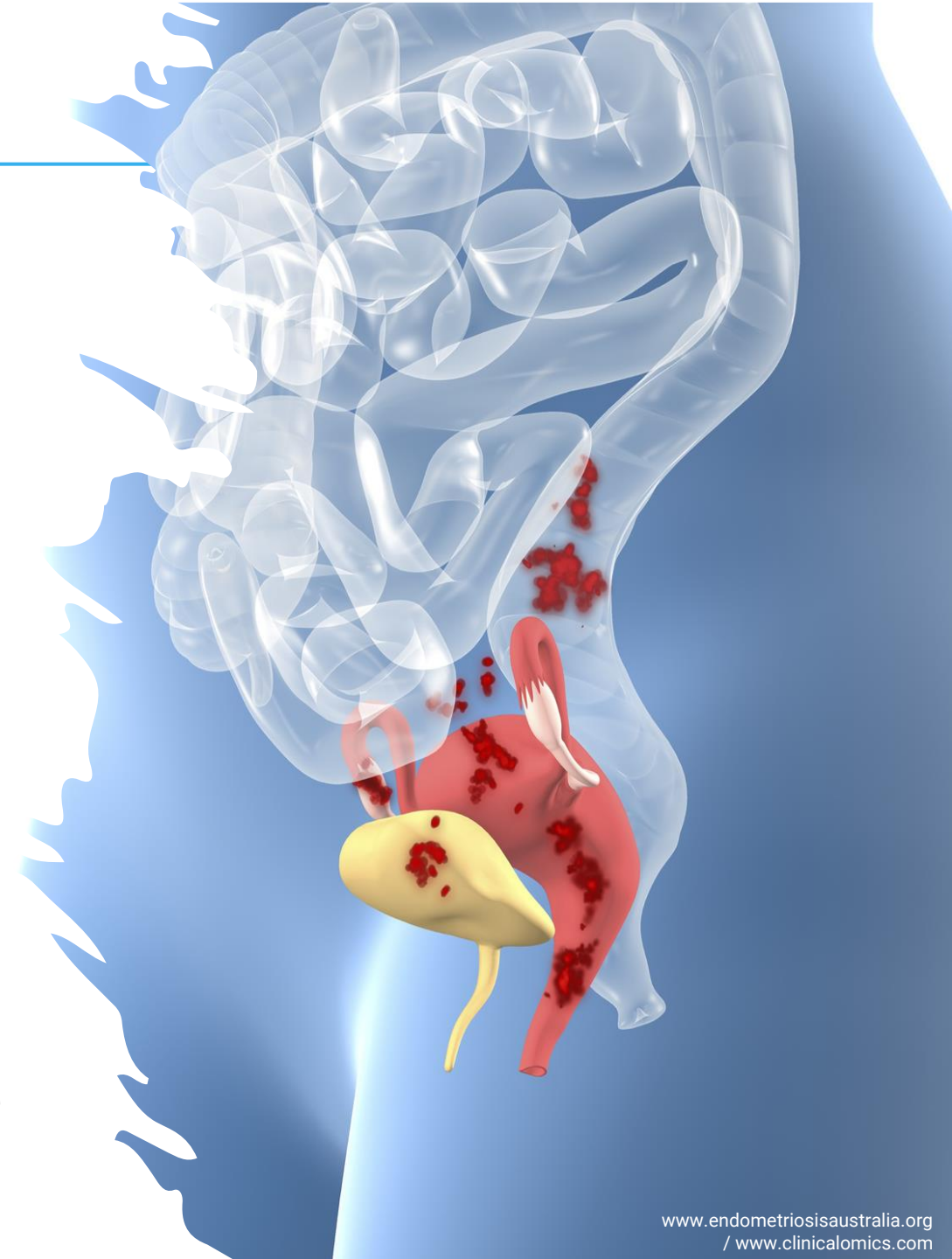
Potential world-first blood test in late-stage development

## Impact of Endometriosis

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

## Promarker™ for Endometriosis

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



# Dx Pipeline: Oesophageal Cancer

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

### Impact of Oesophageal Cancer

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

### Promarker™ for Oesophageal Cancer and Barrett's esophagus

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

# 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

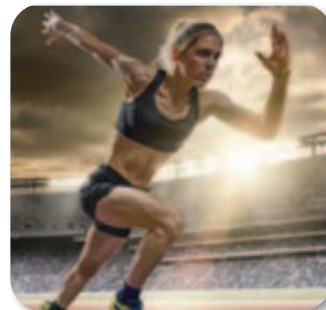
### World first test:

- **Accurate** - highly sensitive
- **Simple to use** – finger prick sample
- **Cost effective** – for mass market use
- **Peer reviewed** – multiple journal publications
- **Patented** – USA, Australia and Japan granted, others pending



### Broad applications of OxiDx technology:

- **Athletic monitoring tool for competition preparedness:**
  - **Professional Sports** – performance, recovery and injury risk management – *55% of sports injuries are muscle related*
  - **Thoroughbred Racing Industry** – injury risk management and race-preparedness - *85% of Thoroughbreds suffer injury in their first 2-3 yrs*
- **Monitoring tool for health and wellbeing:**
  - **Precision Medicine** – tool for self-assessment
  - **Primary Industries** – monitor health in live export & stock production
- **Complementary diagnostic (CDx)**
  - **Clinical Trials** – Utilised to track treatment efficacy and personalised dosing in a range of indications

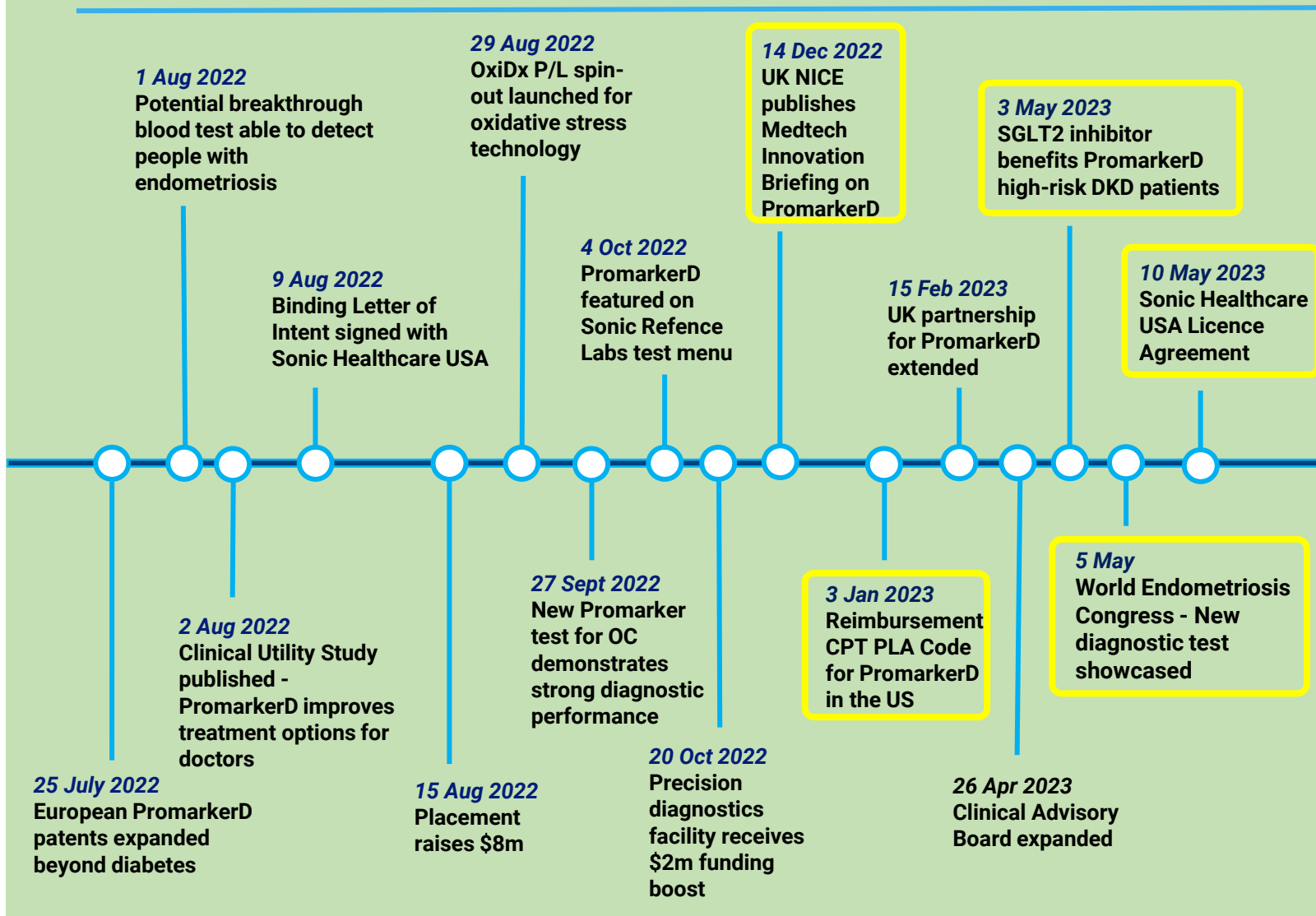


# Timeline & Milestones

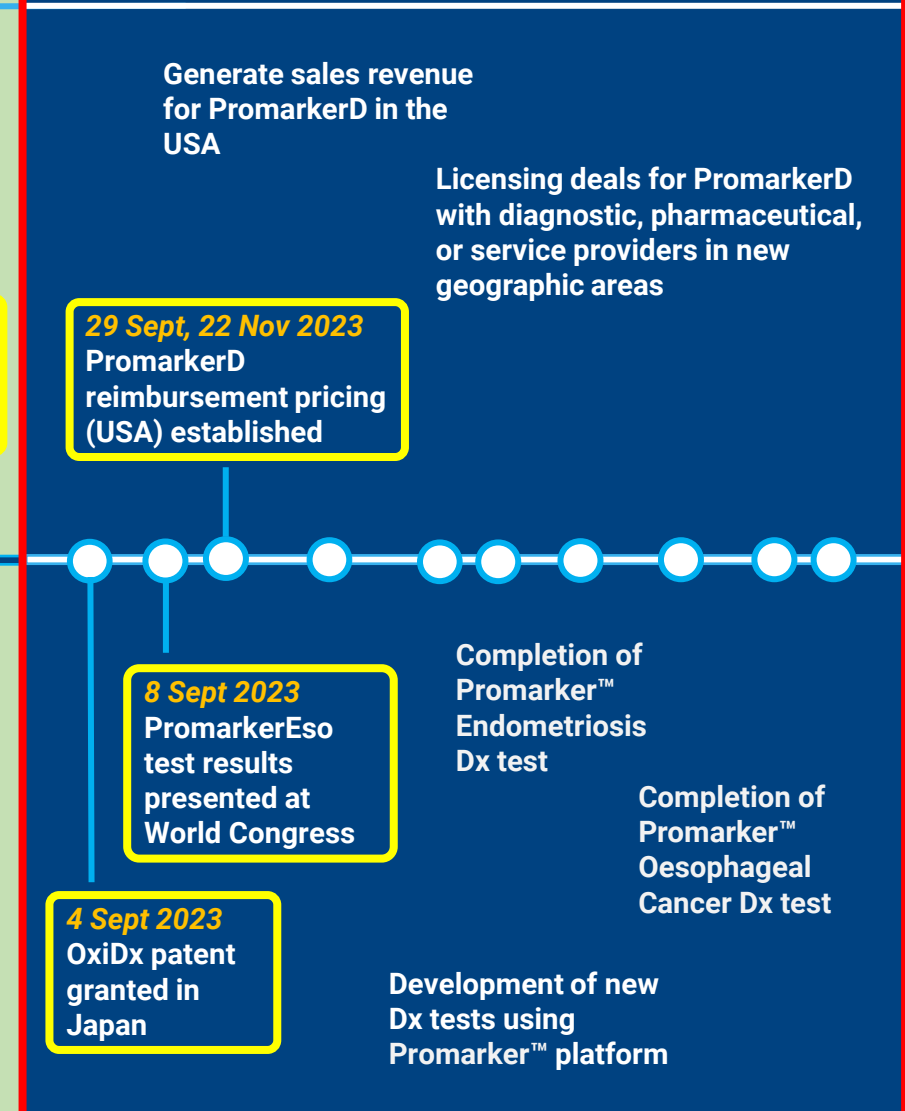


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## FY23 Announcements & Achievements



## FY24 Targets & Milestones



# Value Inflection Points



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## Exceptional Global Opportunity

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

## Share Price Catalysts throughout FY24

| Milestone   | Qtr | 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 – updates                            |     |     |     |     | New first-in-class diagnostic test                           |
| Oesophageal Cancer Dx - updates                       |     |     |     |     | New first-in-class diagnostic test                           |
| Diagnostics Pipeline - updates                        |     |     |     |     | New IP (validation & proof of concept results)               |
| <b>Analytical Services</b>                            |     |     |     |     |  |
| New Contracts   |     |     |     |     | Engages potential future partners & enhances revenue profile |

## **Dr Richard Lipscombe**

### **Managing Director**

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[www.proteomicsinternational.com](http://www.proteomicsinternational.com)

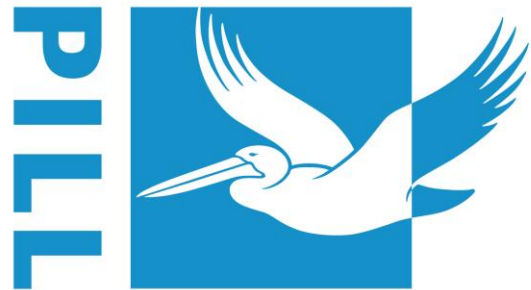
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# **Proteomics International**

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## **Kyle Moss**

### **Corporate Advisor**

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# Supplemental

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ASX: PIQ

# PromarkerD: Key Publications



|   |   |
|---|---|
| <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> .   |
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