



ASX: PIQ

# Proteomics International

LABORATORIES LTD

## JMM Biotech Forum

Investor Presentation

- suite of diagnostics tests primed for launch

10 April 2025

Dr Richard Lipscombe

Managing Director

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# Key Highlights

**A medical technology company at the forefront of precision diagnostics**

*Launching four first-in-class tests driven by a proprietary platform technology:*

PromarkerD

*Diabetic Kidney Disease*

COMMERCIALISATION

- A novel and accurate blood test for predicting the onset of chronic kidney disease in type 2 and type 1 diabetes (DKD)
- DKD leads to **dialysis/kidney transplant**; US reimbursement price USD \$391

PromarkerEndo

*Endometriosis*

DEVELOPMENT

COMMERCIALISATION

- First-in-class blood test identifies all stages of endometriosis with high accuracy (sensitivity and specificity up to 96%)
- Current average 7 years for diagnosis: **replaces diagnostic laparoscopy**

PromarkerEso

*Esophageal Cancer*

DEVELOPMENT

COMMERCIALISATION

- A novel blood test to diagnose esophageal cancer - clinical validation study identified 94% of patients with the disease
- **Caused by chronic acid reflux** (or 'GERD'), 1 in 20 cancer deaths worldwide are due to esophageal cancer: **replaces endoscopy/biopsy**

OxiDx

*Oxidative Stress*

DEVELOPMENT

COMMERCIALISATION

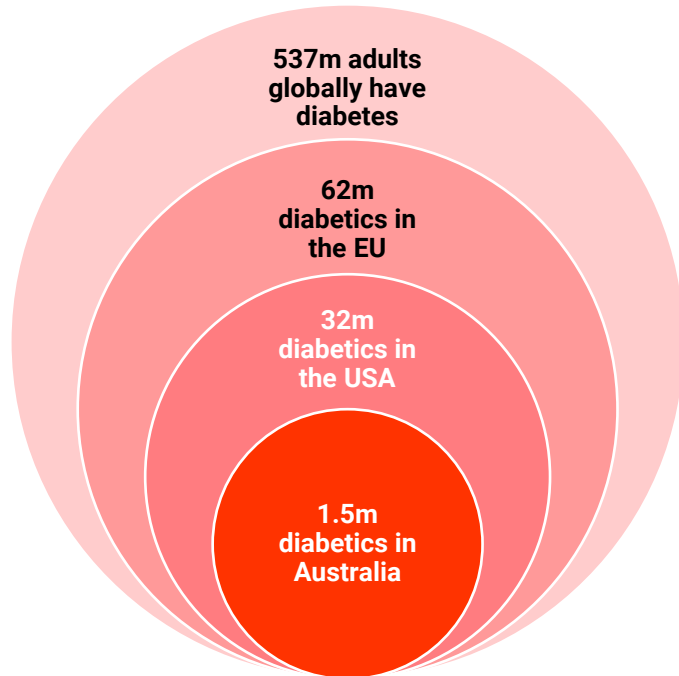
- Groundbreaking results precisely identify muscle damage & assess recovery in high performance athletes; interest from thoroughbred horse racing
- In professional sports muscle damage accounts for 55% of injuries – **\$1.2bn spent treating potentially avoidable injuries in Australia (2023)**

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

Targeting initially the US and Australian markets, with EU and other jurisdictions to follow

## Promarker<sub>D</sub>

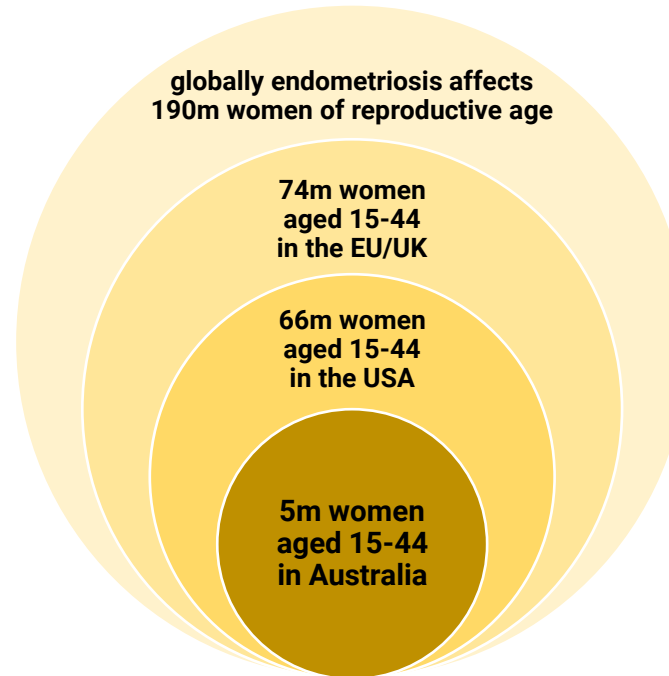
10.5% of the global adult population have diabetes



Target market = 33.5 million adults

## Promarker<sub>Endo</sub>

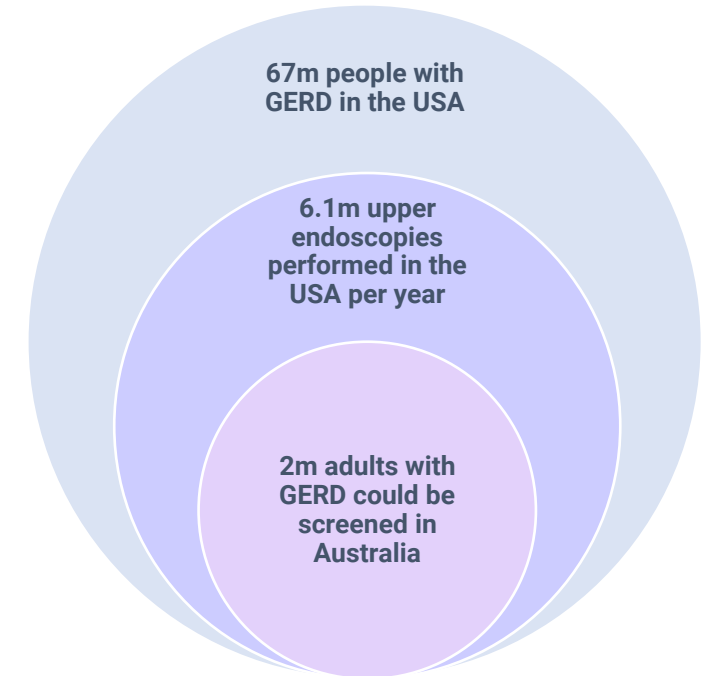
1 in 9 women have endometriosis



Target market = 71 million women

## Promarker<sub>Eso</sub>

10-20% western populations have Gastroesophageal reflux disease (GERD)



Target market = 69 million people



# Go-to-Market Strategy



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*Clinician driven strategy supported by an on-line patient awareness campaign*

**Direct to GPs**



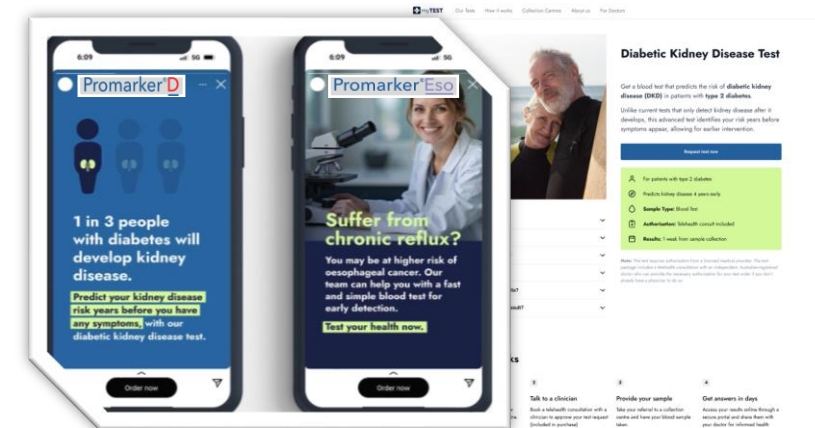
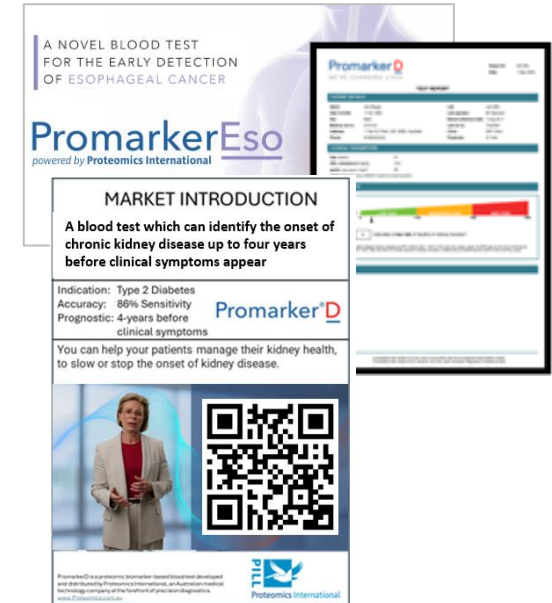
- Target GP Clinics (Australia ~6500 clinics)
- Targeted and research driven awareness program
- Aim to educate & make GPs aware of utility of tests
- Drive adoption of tests through GP clinics
- 96% of US physicians indicated they would likely use PromarkerD to inform clinical decision-making<sup>^</sup>

Increase Awareness  
& Availability of  
Promarker® Tests



**Online awareness  
Campaign**

- Online awareness program for consumers
- Outlines benefits of early intervention
- Allows patients to request test themselves
- Helps patients take control of their health



# Market launch: Australia and USA



	Australia	USA
<b>PI Reference Laboratory</b>	ISO 17025 established ISO 15189 pending	CLIA certification established
<b>Initial capacity of laboratory</b>	PromarkerD: 84,000 pa PromarkerEso/Endo: 32,000 pa	PromarkerD: 84,000 pa PromarkerEso/Endo: 32,000 pa
<b>Launch Date</b>	PromarkerD: Q1 CY25 PromarkerEso/Endo: Q2/Q3 CY25	PromarkerD: Q2 CY25 PromarkerEso/Endo: Q3/Q4 CY25
<b>Proteomics retained test fee</b>	>70% of test sale price	
<b>Reimbursement</b>	Self pay	Self pay & existing CMS code
<b>Pricing</b>	PromarkerD: AUD \$245 PromarkerEso: <i>tba</i> PromarkerEndo: <i>tba</i>	PromarkerD: USD \$391 PromarkerEso: <i>tba</i> PromarkerEndo: <i>tba</i>
<b>Market Size</b>	Diabetes - 1.5 million Endometriosis - 1 in 9 women GERD (Esophageal Cancer) – 2 million	Diabetes - 32 million Endometriosis - 1 in 9 women GERD (Esophageal Cancer) – 67 million

# Multiple Value Drivers in CY25

Milestone	TARGET Qtr	Q4 CY24	Q1 CY25	Q2 CY25	Impact
<b>Commercial</b>					
US reference lab established			✓		Key to first US sales and reimbursement
First Sales PromarkerD in USA					Initiate pathway to significant revenues
Australian clinical lab established			✓		
PromarkerD launched in Australia			✓		Drive global uptake and future revenue
PromarkerEndo launched in Australia					First sales
PromarkerEso launched in Australia					<i>Launch imminent (Advisory Board announced)</i>
<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>Reimbursement</b>					
PromarkerD PLA code (US) application			✓		Support US roll-out

# Summary – *Exceptional Growth Opportunity*

- **Disruptive, cutting-edge technology & proven in-house diagnostics platform**
- **Multiple patented tests**
  - PromarkerD test de-risked, patented, commercial launch ready
  - PromarkerEso, PromarkerEndo and OxiDx tests nearing market entry
  - Tests are scalable with high margins – and address large markets
- **Team, infrastructure and certifications in place to support commercial launches**
- **First sales in the first half of this year (H1 CY25)**



## **Dr Richard Lipscombe**

### **Managing Director**

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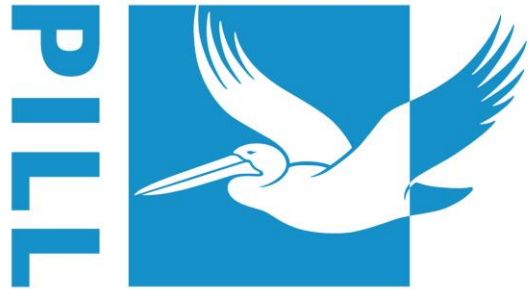
## **Dirk van Dissel**

### **Investor Relations**

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# **Proteomics International**

LABORATORIES LTD

# Corporate Overview

## Corporate Snapshot

ASX code	PIQ
Market Capitalisation	A\$55m
Cash (31 Dec 2024)	A\$5.3m
Share Price (4 April 2025)	A\$0.42
Shares on issue	131m
Revenue & other income – FY24	A\$3.6m
Average Quarterly cash burn – FY24	A\$1.6m



## Financial and Corporate

- Top 40 Shareholders hold 41%
- Directors are highly aligned with shareholders holding 13%
- Revenue generating
  - Bioanalytical service business helps offset cash burn
  - Launching four tests in 2025 for sales of PromarkerD, PromarkerEso, OxiDx & PromarkerEndo
- Corporate
  - Board renewal: Industry experienced Chair and NED appointed
  - Recruited senior executives to accelerate test commercialisation
- State-of-the-art laboratories
  - Specialist proteomics technology platform
  - Cutting edge facility with world leading accreditation: ISO 17025 (analytical) and ISO 13485 (manufacturing), expanding to include ISO 15189 (clinical testing)
  - US clinical reference laboratory established (CLIA certified)
  - Analytical services – pharmacokinetic (PK) testing & biosimilars
  - Headquartered on QEII Medical Campus, Perth, WA

# Commercialisation Team

*Dedicated team responsible for driving commercial adoption*



**Phillip Prather**  
*Chief Commercial Officer*

Phillip brings extensive leadership in the global medical devices industry, particularly in developing new markets and successfully launching products for innovative companies including Cochlear, QIAGEN, Philips, Medtronic, and Leo Cancer Care. His experience includes regulatory, quality, and market access across major medtech markets (EU, North America, APAC). Philip is responsible for global sales, marketing, and customer engagement activities.



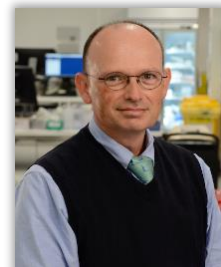
**Jacqueline Gray**  
*Chief Financial Officer & Head of Corporate Development*

Jacqueline has held senior leadership roles with global media and healthcare companies, including the Economist, BBC Worldwide, and National Medical Enterprises. More recently her focus has been with high growth, emerging businesses in medical technology, Software as a Service (SaaS), digital marketing and e-commerce. Jacqueline has experience in M&A, business restructuring, and managing businesses during disruption, downturn, and exponential growth.



**Dr Pearl Tan**  
*Head of Product Development*

Pearl is responsible for the commercial delivery of the Promarker® pipeline. Since joining Proteomics International in 2014, Pearl has successfully led the manufacturing of the PromarkerD test, regulatory & PLA code submissions, and most recently the establishment of the Company's CLIA certified lab in the USA.



**Dr Johan Conradie**  
*Clinical Pathologist*

Johan is a Chemical Pathologist with over 21 years of experience in clinical biochemistry and toxicology, and gained his FRCPA in 2008 and later completed an MBA at the University of Western Australia in 2019. Johan also serves as the Medical Director of Western Diagnostic Pathology. Johan has overall responsibility for clinical results from the suite of Promarker® diagnostic tests.



# Board of Directors



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## **Dr James Williams** PhD (Melbourne), MBA (UWA), BSc, Hons (Aberdeen), GAICD, Non-Executive 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 and diagnostics.



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

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



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

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



## **Neville Gardiner** BBus (Accounting and Business Law) (Curtin), Non-Executive Director

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.



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

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

PromarkerD

*Diabetic Kidney Disease*

COMMERCIALISATION

PromarkerEndo

*Endometriosis*

DEVELOPMENT

COMMERCIALISATION

PromarkerEso

*Esophageal Cancer*

DEVELOPMENT

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OxiDx

*Oxidative Stress*









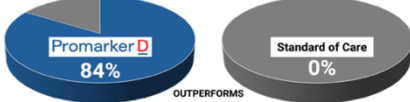




DEVELOPMENT

COMMERCIALISATION

Supplemental – the Promarker® suite of diagnostic tests



# PromarkerD: Diabetic Kidney Disease

Intellectual Property		Patents granted in all major jurisdictions - PromarkerD Patent family & Trademark covers <b>72%</b> of the world's diabetes patients
Regulatory		<b>CE Mark</b> (EU) registration received for the PromarkerD Immunoassay IVD US sales utilising Lab Developed Test (LDT) pathway via CLIA certified laboratories; Australia utilising ISO 15189 pathway 
Manufacturing scale-up		ISO 13485 certified EU manufacturer Simple technology platform (immunoassay) – easy to use and integrate into existing pathology lab processes
Peer Reviewed		PromarkerD tested on over <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
Physician Support		<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.
Outperforms Standard of Care		857 community-based patients tested for existing DKD at baseline: 497 had normal kidney function PromarkerD accurately predicted 84% (N=38); All were missed by Standard of Care tests 
The Need		<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
The Treatments		<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
The Utility		<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
Breakthrough Study		<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

# My impression on Promarker®D market release

*What are our Key Opinion Leaders saying?*



**Professor Merlin Thomas**, MBChB, PhD, FRACP, FAAHMS  
Nephrologist  
Department of Diabetes, Monash University, Australia

*"When kidney function is lost, it is lost forever. Identifying people at increased risk of developing impaired kidney function before this function is irreversibly gone is the best way to protect their kidneys and their health."*

*The saddest thing you hear as a nephrologist is the regret, "I wish I had known earlier!"*

*"There has been a sea-change in relation to the management of cardiorenal metabolic disorders with the recognition of the need to take a more preventative approach rather than waiting until cardiorenal damage has occurred."*

*Waiting for the appearance of albuminuria and cardiovascular disease should no longer be our number one priority and PromarkerD may offer people with diabetes an opportunity to manage risk before damage has occurred."*



**Dr Andrew Frankel**, MBBS, BSc, MD, FRCP  
Consultant Physician and Nephrologist  
Imperial College Healthcare NHS Trust, UK

# PromarkerEso: Esophageal Cancer

## *First-in-class blood test 'PromarkerEso' ready for commercialisation*

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

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

### **Test status**

- **Test shows 94% accuracy** in diagnosing patients with and without the disease  
(World Congress Esophageal Diseases, 2024)
- Advanced statistical modelling being refined using 'traffic light' system to **improve test performance for clinical use**
- New clinical results **submitted for peer review publication**
- Methodology (mass spectrometry) being **adapted for clinical launch**
- **Patents granted in Europe, China, Australia**; USA pending
- Discussions underway to establish test in reference laboratories worldwide
- Proteomics International preparing to **launch PromarkerEso in Australia** under ISO 15189 accreditation, now targeting **Q2 CY25**

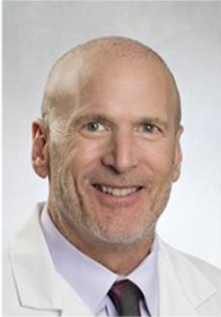
***A non-invasive blood test for esophageal cancer could transform the way this disease is detected and is attracting interest from world leaders in EAC treatment***

### **Clinical studies**

- *Development and Validation* - Collaboration with QIMR Berghofer Medical Research Institute analysed 302 samples across two patient cohorts: (World Congress Esophageal Diseases, 2023)
  - ❑ PROBE-NET study, Australia (N=249)
  - ❑ Ochsner Health System, USA (N=49)
- *Clinical validation* - biomarker panel confirmed in independent patient cohort from Victoria Cancer Biobank (N=165)  
(Lorne Proteomics Symposium, Feb '24)
- *Clinical validation* – analysis of samples from Victoria Cancer Biobank confirmed clinical performance of the test (N=165)  
(World Congress Esophageal Diseases, 2024)

# My impression on Promarker<sup>®</sup>Eso market release

*What are our Key Opinion Leaders saying?*



**Professor Robert Odze, MD, FRCPc**  
Senior Consultant Pathologist, Professor of Pathology  
Tufts University Medical School, USA

*"As a pathologist, I am keenly aware of the multitude of problems and limitations we have regarding detection of esophageal cancer and its precursors based on tissue analysis.*

*Proteomic biomarker serum analysis represents a new approach that would greatly reduce the current problems we face in cancer detection and enable better early and more accurate risk prediction.*

*Incorporating serum-based biomarkers that can be used in the general population will enhance our ability to detect cancer and save lives, both of which are in great need for patients at risk for esophageal cancer"*


*"The early, prompt detection and precise risk assessment of esophageal adenocarcinoma will enable curative treatment for this disease. Advanced diagnostics, in particular PromarkerEso, are proving to be an important and effective way to transform the outcomes for our patients"*



**Professor Hugh Barr, MD (Dist), ChM, FRCS, FRCSE, FHEA, FOD**  
Consultant General & Gastrointestinal Surgeon  
Gloucestershire Hospitals NHS Foundation Trust, UK



# PromarkerEndo: Endometriosis



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## First-in-class blood test 'PromarkerEndo' nearing commercialisation

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

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

### Test status

- **Excellent diagnostic performance published for prototype PromarkerEndo test in identifying all stages of endometriosis with high accuracy** (*Human Reproduction* 2024)
  - endo vs healthy controls: Sensitivity 96%, Specificity 98%
  - stage IV endo vs symptomatic controls: Sensitivity 98%, Specificity 96%
  - stage I endo vs symptomatic controls: Sensitivity 87%, Specificity 72%
- Advanced statistical modelling being finalised using 'traffic light' system to **improve test performance for clinical use**
- Methodology (mass spectrometry) being **adapted for clinical launch**
- **Patents pending** in all major jurisdictions
- Discussions underway to establish test in reference laboratories worldwide
- Proteomics International preparing to **launch PromarkerEndo in Australia** under ISO 15189 accreditation, now targeting **Q2/Q3 CY25**

*A non-invasive blood test for endometriosis is a potential 'game-changer' in women's health and the published results have attracted interest worldwide*

### 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=464; healthy individuals N=153; symptomatic controls N=132) (*World Endometriosis Conference, May '23*)
- *Confirmation results* - Peer reviewed and published (*Journal Human Reproduction, Dec 24*)
- *Further studies* - Collaboration ongoing with University of Oxford for international validation study (N=600 samples)



## Groundbreaking blood test nearing commercialisation

### 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

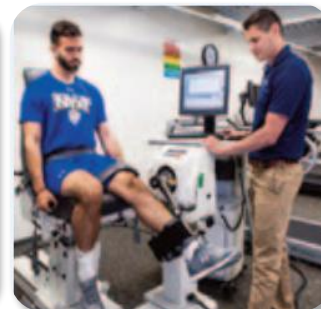
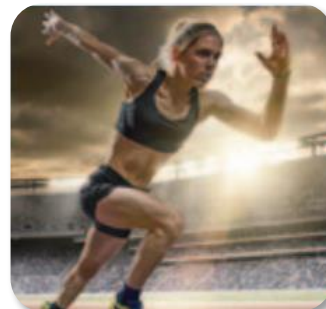
**OxiDx**

### 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
    - World first results published showing **OxiDx test can identify muscle damage and assess recovery in elite athletes** (*Physiological Reports*, Dec 2024)
  - **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](#)

### New commercialisation pathways:

- Potential spin-out or partnering opportunity across sports & horse racing industries
- Proteomics International preparing to **launch OxiDx in Australia** under ISO 17025 accreditation, targeting **Q3 CY25**



## Identity

Proteomics International is a medical technology company specialising in predictive diagnostics and advanced analytical services using proteomics – the industrial scale study of the structure and function of proteins.

## Mission

To improve the quality of lives by the creation and application of innovative tools that enable the improved treatment of disease.

## Vision

To help create a world where disease is detected early and cured simply.