

**ASX Release** 10 April 2025

**ASX code: PIQ** 

#### **Investor Presentation** JMM Biotech Forum

Proteomics International Laboratories Ltd (Proteomics International; the Company; ASX: PIQ), a pioneer in precision diagnostics, is pleased to announce its Managing Director Dr Richard Lipscombe will give the attached investor presentation at the JMM Biotech Forum, a virtual event hosted today by Jane Morgan Management.

Authorised by the Chair and the Managing Director on behalf of the Board of PIQ.

**ENDS** 

#### About Proteomics International Laboratories (PILL) (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 bioanalytical 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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## Disclaimer



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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:



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



**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



Esophageal Cancer

VELOPMENT 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



**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



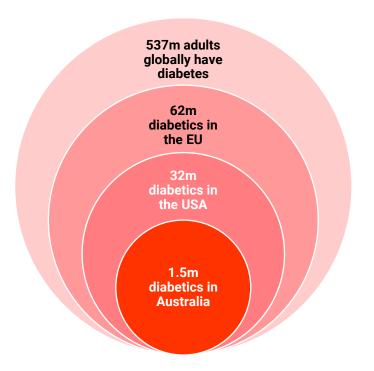
10.5% of the global adult population have diabetes



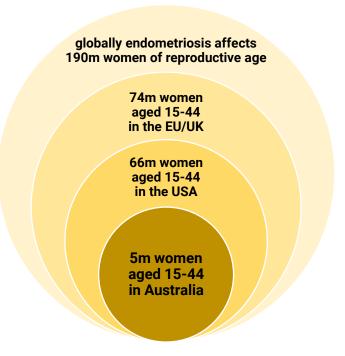
1 in 9 women have endometriosis

# **Promarker**Eso

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

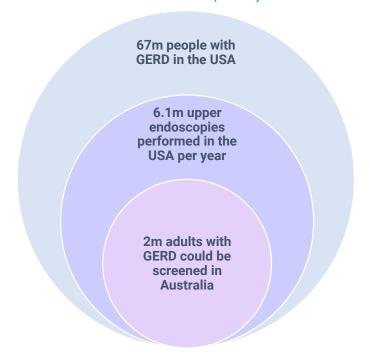


Target market = 33.5 million adults



**Target market = 71 million women** 

www.marchofdimes.org/peristats

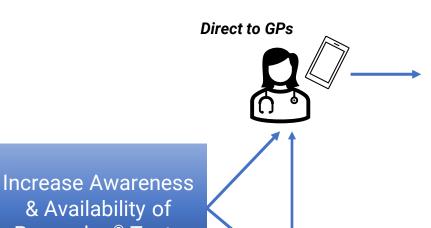


**Target market = 69 million people** 

# **Go-to-Market Strategy**



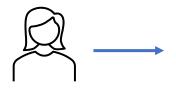
## Clinician driven strategy supported by an on-line patient awareness campaign



- 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^



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

# Multiple Value Drivers in CY25



Milestone	TARGET Qtr	Q4 CY24	Q1 CY25	Q2 CY25	Impact
Commercial				_	
US reference lab established			<b>✓</b>		Key to first US sales and reimbursement
First Sales PromarkerD in USA					Initiate pathway to significant revenues
Australian clinical lab established			<b>√</b>		
PromarkerD launched in Australia			<b>√</b>		Drive global uptake and future revenue
PromarkerEndo launched in Australia	a				First sales
PromarkerEso launched in Australia					Launch imminent (Advisory Board announced)
Clinical/Technical					
Endometriosis Dx - results update		<b>√</b>			New first-in-class diagnostic test
Esophageal Cancer Dx - results upda	te	<b>√</b>			New first-in-class diagnostic test
OxiDx test - results update		<b>√</b>			New first-in-class diagnostic test
Reimbursement					
PromarkerD PLA code (US) applicati	on		<b>✓</b>		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)

## Contact



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**ASX:PIQ** 

## **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
Average Quarterly Cash Dufff = F124	ΑŞ



### **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



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PHILIPS
Chlear Clacen

Medtronic

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.



BBC Worldwide The Economist

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 ecommerce. Jacqueline has experience in M&A, business restructuring, and managing businesses during disruption, downturn, and exponential growth.



Promarker D
WE'RE CHANGING LIVES

**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.



II western

### **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**





#### 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, BHIthSc (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).



Supplemental – the Promarker® suite of diagnostic tests

# PromarkerD: Diabetic Kidney Disease



**Intellectual Property** 



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

Regulatory



CE Mark (EU) registration received for the PromarkerD Immunoassay IVD
US sales utilising Lab Developed Test (LDT) pathway via CLIA certified laboratories; Australia utilising ISO 15189 pathway



Manufacturing scaleup



ISO 13485 certified EU manufacturer

Simple technology platform (immunoassay) – easy to use and integrate into existing pathology lab processes

**Peer Reviewed** 



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

Global multi-centre clinical study (CANVAS) on 3,568 participants in collaboration with Janssen (J&J) Janssen Clinical & analytical validity proven (Sensitivity 86%); 10+ Peer Reviewed Publications

**Physician Support** 

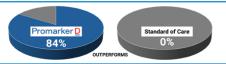


**Clinical utility demonstrated** - US based survey showed **96**% of physicians were likely to use PromarkerD test scores for clinical decision making; PromarkerD consistently ranked as one of the top 2 factors driving physician decision-making.

Outperforms Standard of Care



857 community-based patients tested for existing DKD at baseline: 497 had normal kidney function PromarkerD accurately predicted 84% (N=38); All were missed by Standard of Care tests



The Need



**Economic Cost**: Chronic Kidney Disease cost Australia A\$9.9bn in 2021 (Kidney Health Australia) - investment in early detection could yield a net benefit of \$10.2bn over 20 years; Kidney Research UK have declared a public health emergency - by 2033 kidney disease risks costing the UK economy £13.9bn annually

The Treatments



**New renal protective therapies:** SLGT2-inhibitors approved & potential use of GLP-1 agonist semaglutide (Ozempic) PromarkerD identifies patients for better management of diabetes, adherence to medications, and focus on diet & exercise

The Utility



**Complementary diagnostic** - Early diagnosis of DKD using PromarkerD can help inform doctors' treatment decisions to improve clinical outcomes for patients. Actions taken BEFORE the onset of DKD

**Breakthrough Study** 



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

# 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®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"



## PromarkerEndo: Endometriosis



## First-in-class blood test 'Promarker Endo' 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)

## OxiDx: Oxidative Stress



## 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



#### **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









19

Australian Institute of Health and Welfare | Appraising the Welfare of Thoroughbred Race horses in Training | doi: 10.1373/clinchem.2005.061408

## Proteomics International (Est'd 2001)



## 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.