

ASX Release 25 January 2024

ASX code: PIQ

Investor Presentation

Proteomics International Laboratories Ltd (Proteomics International; the Company; ASX: PIQ) is pleased to release a copy of its latest investor presentation.

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

ENDS

About Proteomics International Laboratories (PILL) (www.proteomicsinternational.com)

Proteomics International (Perth, Western Australia) is a wholly owned subsidiary and trading name of PILL (ASX: PIQ), a medical technology company at the forefront of predictive diagnostics and bio-analytical services. The Company specialises in the area of proteomics - the industrial scale study of the structure and function of proteins. Proteomics International's mission is to improve the quality of lives by the creation and application of innovative tools that enable the improved treatment of disease.

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Proteomics International Laboratories Ltd



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

Three key focus tests driven by a proprietary platform technology:



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



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



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 Overview



Corporate Snapshot	
ASX code	PIQ
Market Capitalisation (Post January '24 Placement)	A\$111m
Cash (31 Dec 2023 + Placement Proceeds)	~A\$11m
Share Price (24 Jan 2024)	A\$0.85
Shares on issue (Post January 24 Placement)	131m
Revenue & other income – H1 FY24	A\$2.3m
Average Quarterly cash burn – H1FY24	A\$1.6m
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Financial and Corporate

- Top 40 Shareholders hold 54%
- Directors are highly aligned with shareholders holding 14%
- Institutional placement raised \$6.5m with leading Asian and Australian funds participating [ASX: 23 January 2024]
- State-of-the-art laboratories
 - Accredited (ISO 17025 and ISO 13485) cutting-edge facility
 - Specialist proteomics technology platform
 - Analytical services pharmacokinetic (PK) testing & biosimilars
 - Headquartered on QEII Medical Campus, Perth, WA
- Revenue generating
 - Bioanalytical service business helps offset cash burn
 - Current revenue does not include any major sales of PromarkerD

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

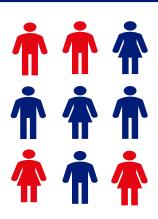
Proven track record in product development, clinical trials, regulatory affairs, audits, quality management, project management and operational strategy. Dr Elliott is Executive Director, Strategic Fractionation Program Delivery at CSL Behring, a subsidiary of CSL Limited. She is also a non-executive director of PolyNovo Limited (ASX:PNV).

Promarker – Platform Technology





PromarkerTM is a platform technology that can identify unique protein biomarkers 'fingerprints'

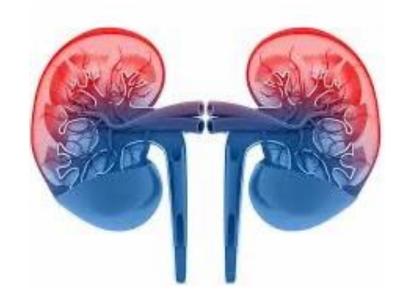


The platform identifies and links the unique protein biomarkers to specific diseases, enabling Proteomics International to create novel diagnostic tests

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



Current standard-of-care diagnostics

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



Diseased Kidney



Promarker D

- PromarkerD can predict the onset of disease before clinical symptoms appear (up to four years prior)
- Doctors can then prescribe an early therapeutic treatment to slow or stop the onset of disease
- Kidneys remain healthier for longer, saving healthcare systems billions of dollars and improving quality of life for patients



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,

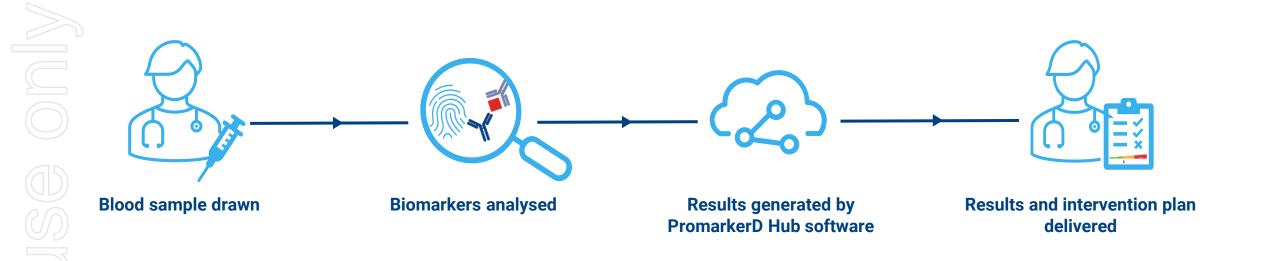
FADCES - United States

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

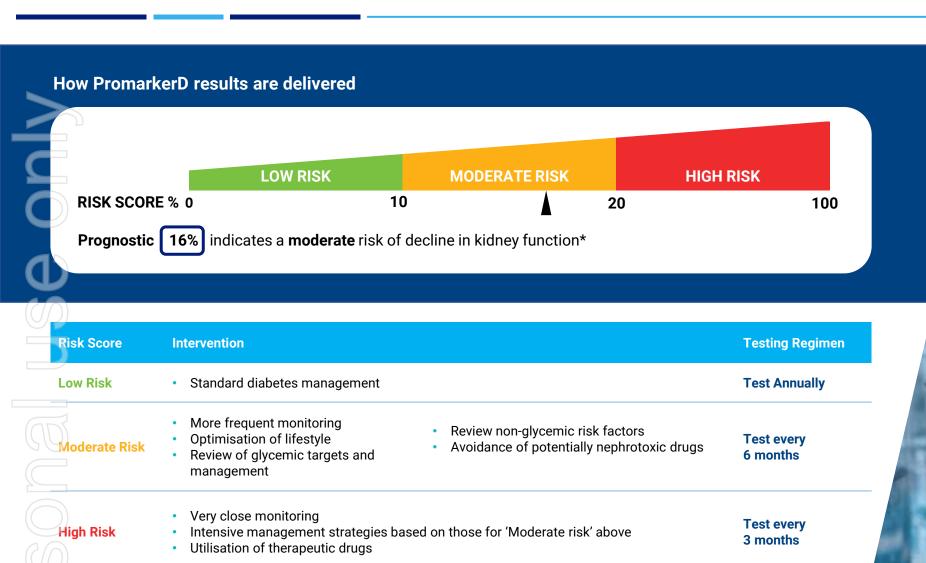
Clinician delivers results to patient

Depending on results, intervention may include:

- change of lifestyle; and/or
- therapeutic drugs
 - SGLT2-inhibitor
 - GLP-1 agonist

PromarkerD - Results & Intervention





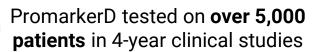
^{**} as defined by incident diabetic kidney disease (eGFR <60ml/min/1.73m²) in the next four years. Note: if eGFR level at the time of the test is already 460ml/min/1.73m², then the risk of a further decline in kidney function is defined as an eGFR decline >30% in the next four years

PromarkerD in the Clinic





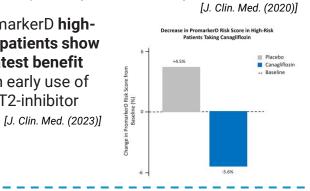
Peer Reviewed



10+ Peer Reviewed Publications

World leading results: janssen

- 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 = $1.3x10^{-104}$)
- PromarkerD highrisk patients show greatest benefit from early use of SGLT2-inhibitor





Physician Support

Survey of 400 Endocrinologists & Primary Care Physicians (US based)

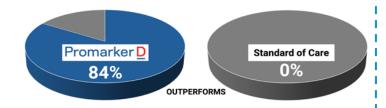
- **96% of physicians** were likely to use PromarkerD test scores for clinical decision making
- PromarkerD consistently ranked as one of the top 2 factors driving physician decisionmaking:
 - monitoring frequency
 - use of anti-inflammatories
 - prescribing SGLT2s
 - ACE inhibitor dosing

[PLOS One (2022)]



Outperforms Standard of Care

- 857 community based patients tested for existing DKD at baseline: 497 had normal kidney function
- 9% of patients developed DKD within 4 years:
 - PromarkerD accurately predicted 84% (N=38)
 - All were missed by Standard of care tests [ASN (2021)]



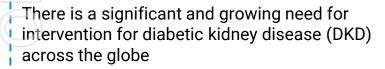
PromarkerD compared to standard of care tests (eGFR and ACR) for predicting DKD

PromarkerD: Precision Medicine



Promarker D

The Need



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, canaglifozin, dapagliflozin) have now been approved for treatment of DKD
- GLP-1 agonist semaglutide (Ozempic) trial for DKD shows treatment is renal protective



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



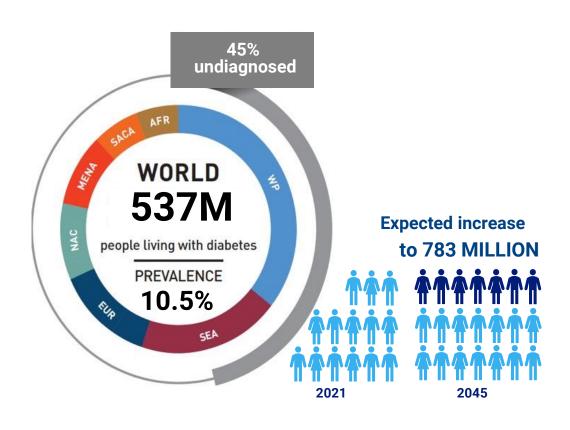
Diabetic Kidney Disease is becoming one of the largest burdens on healthcare systems globally

Patent family & Trademark covers 72% of world's diabetics¹

Country	Patent/Application No	Patent Status	No. Diabetics ¹
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 ^{2,3}	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 ^{2,4}	US 9,146,243	Granted	32,215,300

~368 million Total

- 1. International Diabetes Federation (IDF) Atlas 10th 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
- USA patent further extended to cover method for identifying drugs for abnormal kidney function using one of the PromarkerD biomarkers (CD5L)



Market assumptions

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

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





Sonic is the <u>third</u> Largest laboratory medicine company in the US



Test listed on Sonic website & commercial launch expected in Q2 CY24



Sonic has labs spanning from Hawaii to Boston



Reimbursement in the US



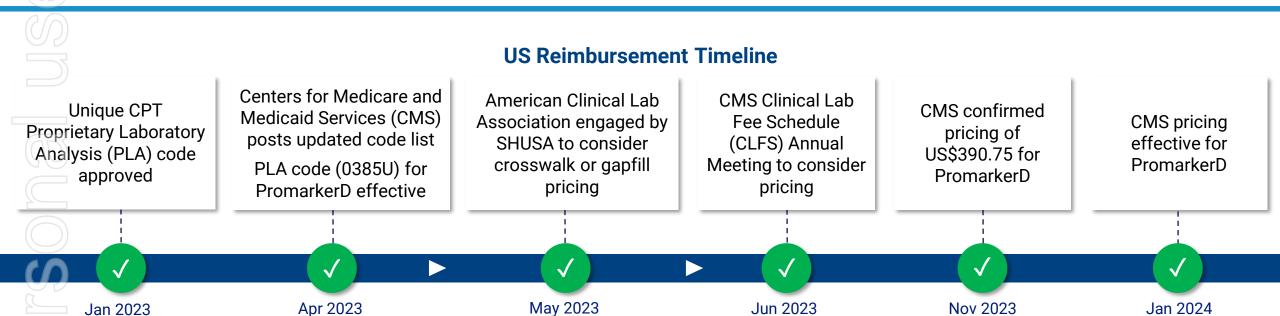
Proteomics International has worked with its partner Sonic Healthcare USA to achieve reimbursement in the US

CMS is the federal agency in the United States that administers Medicare and Medicaid

Medicare and Medicaid collectively responsible for 42% of healthcare spending in the US

CMS has assigned a payment rate of US\$390.75 for PromarkerD

CMS is responsible for providing healthcare coverage to more than 100m Americans



Target Markets: PromarkerD



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



- 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



- Licence with Omics Global Solutions for immunoassay (Innovatio ND2): Puerto Rico, Dominican Republic, and Chile
- 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



Detailed market assessments completed; discussions ongoing

Next Steps

Actively targeting potential partners in key jurisdictions

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Pipeline of Precision Diagnostics

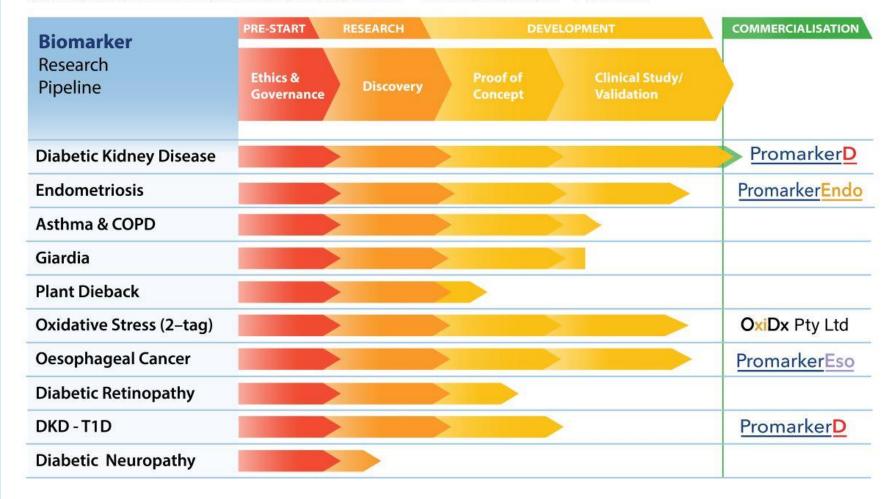


Platform technology drives deep pipeline of novel diagnostic tests

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

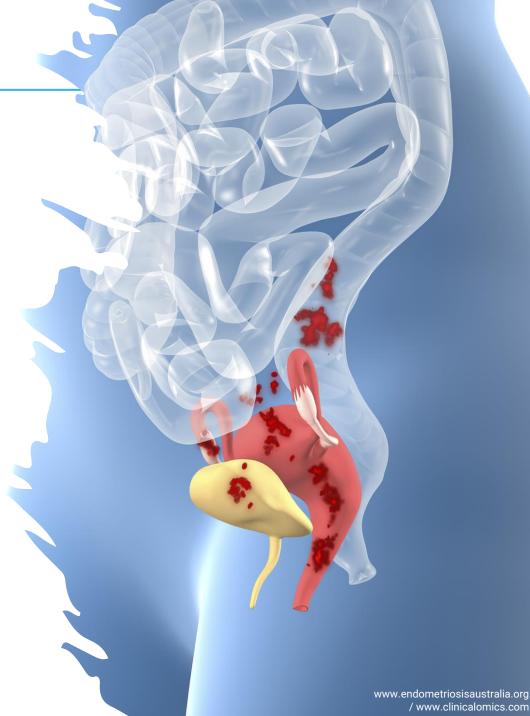
Potential world-first blood test in late-stage development

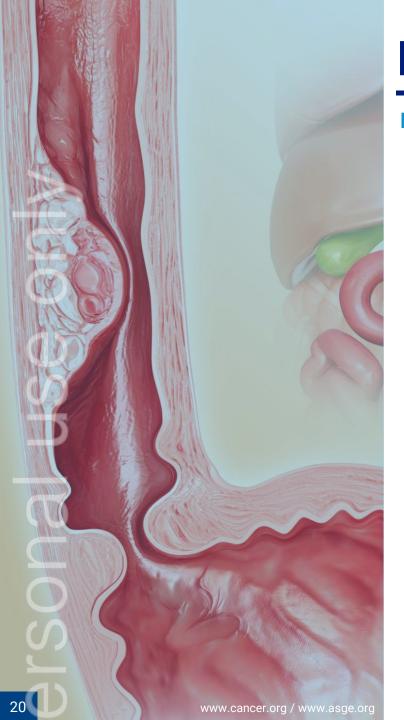
Impact of Endometriosis

- 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

PromarkerTM 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 (premalignant) which affects 1-2% of adults and can arise from chronic acid reflux

PromarkerTM 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

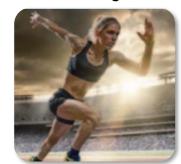
World first test:

- 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 racepreparedness - 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



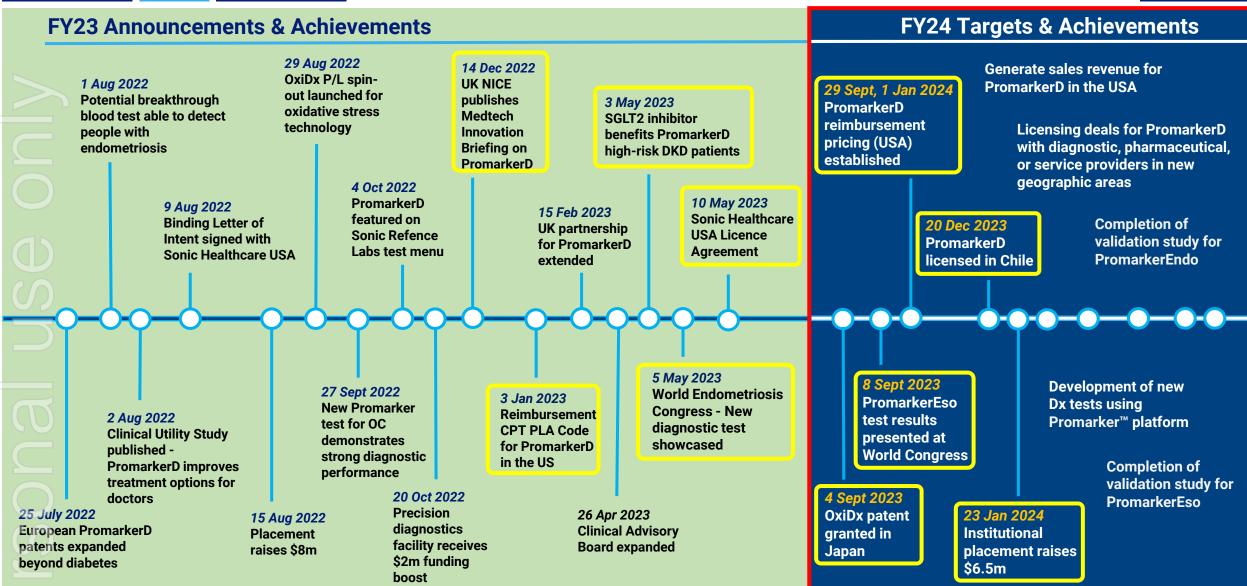






Timeline & Milestones





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	Dec	Mar	Jun	Impact
PromarkerD					
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
Promarker™					
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)
Analytical Services					
New Contracts					Engages potential future partners & enhances revenue profile

Contact



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Supplemental





PromarkerD: Key Publications



PromarkerD Demonstrates Benefit of Early Treatment with SGLT2-inhibitors	Peters KE, et al. Canagliflozin Attenuates PromarkerD Diabetic Kidney Disease Risk Prediction Score. J Clinical Medicine. <u>2023.</u>				
Clinical Utility	Fusfeld L, et al. Evaluation of the clinical utility of the PromarkerD in-vitro test in predicting diabetic kidney disease and rapid renal decline through a conjoint analysis. PLOS ONE. <u>2022.</u>				
PromarkerD vs Standard of Care	Peters KE, et al. A Comparison of PromarkerD to Standard of Care Tests for Predicting Renal Decline in Type 2 Diabet Poster presented at ASN Kidney Week. <u>2021.</u>				
Economic Health Benefit	Burchenal W, et al. Demonstrating the Economic Health Benefit of using the PromarkerD In Vitro Diagnostic Test in the Prediction of Diabetic Kidney Disease. Poster presented at the American Diabetes Association's 81st Scientific Sessions. 2021.				
Global Multi-centre Validation	Peters KE, et al. PromarkerD Predicts Renal Function Decline in Type 2 Diabetes in the Canagliflozin Cardiovascular Assessment Study (CANVAS). Journal of Clinical Medicine. <u>2020.</u>				
Predicts Late-stage Renal Function Decline	Peters KE, et al. PromarkerD Predicts Late-Stage Renal Function Decline in Type 2 Diabetes in the Canagliflozin Cardiovascular Assessment Study (CANVAS). Poster presented at ADA. <u>2022.</u>				
Prognostic Validation	Peters KE, et al. Validation of a Protein Biomarker Test for Predicting Renal Decline in Type 2 Diabetes: The Fremantle Diabetes Study Phase II. J Diab Comp. <u>2019.</u>				
Prognostic Development	Peters KE, et al. Identification of Novel Circulating Biomarkers Predicting Rapid Decline in Renal Function in Type 2 Diabetes: The Fremantle Diabetes Study Phase II. Diabetes Care. <u>2017.</u>				
Diagnostic Study	Bringans SD, et al. Comprehensive Mass Spectrometry Based Biomarker Discovery and Validation Platform as Applie to Diabetic Kidney Disease. EuPA Open Proteomics. <u>2017.</u>				
Cross-platform Validation	Bringans SD, et al. The New and the Old: Platform Cross-Validation of Immunoaffinity MASS Spectrometry versus ELI for PromarkerD, a Predictive Test for Diabetic Kidney Disease. Proteomes. <u>2020.</u>				
Cross-over Validation	Bringans SD, et al. A Robust Multiplex Immunoaffinity Mass Spectrometry Assay (PromarkerD) for Clinical Prediction of Diabetic Kidney Disease. Clin Proteomics. <u>2020.</u>				