Proteomics International
LABORATORIES LTD

ASX: PIQ

AGM Presentation

8 November 2024

Dr. Richard Lipscombe
Managing Director

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Proteomics International Laboratories Ltd

ASX: PIQ

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

Commercialising three first-in-class tests driven by a proprietary platform technology:

PromarkerD — *Diabetic Kidney Disease* — COMMERCIALISATION

- A novel and accurate test for predicting the onset of chronic kidney disease in type 2 and type 1 diabetes (DKD)
- 10.5% of adults worldwide currently have diabetes
- US reimbursement price set at US$390

PromarkerEndo — *Endometriosis* — DEVELOPMENT / COMMERCIALISATION

- A novel and accurate test to diagnose endometriosis
- Affects 1 in 9 women and costs Australia alone over AU$10Bn a year
- Test identified up to 90% of patients with the disease

PromarkerEso — *Esophageal Cancer* — DEVELOPMENT / COMMERCIALISATION

- A novel and accurate test to diagnose esophageal cancer
- 1 in 20 cancer deaths worldwide due to esophageal cancer
- Clinical validation study: test identified 94% of patients with the disease

Corporate Overview

ASX: PIQ

Corporate Snapshot

ASX code	PIQ
Market Capitalisation	A$91m
Cash (30 Sept 2024) (+ R&D Tax Incentive ~$2m H1 FY25)	~A$5.1m
Share Price (6 Nov 2024)	A$0.70
Shares on issue	131m
Revenue & other income – FY25	A$2.7m
Average Quarterly cash burn – FY25	A$1.5m

Financial and Corporate

- Top 40 Shareholders hold 41%
- 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 sales of PromarkerD, PromarkerEndo or PromarkerEso
- Corporate
  - Board renewal progressed
  - Finalising recruitment of senior executives to accelerate commercialisation of 3 lead tests

Science Proven – Commercialisation Underway

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Over 20 years R&D experience resulting in deep pipeline

- 3 highly accurate tests commercialisation ready
- Large unmet medical needs
- Will save patient lives & improve quality of life
- Save healthcare systems billions of dollars

Each test has whole of market appeal

- Pharma
- Clinical pathology labs
- Diagnostic platform developers
- Physicians
- Patients

New commercial opportunities for specialised tests

- Changes to regulatory pathways are opening the door to launching specialised tests
- 320,000 CLIA certified labs in the USA
- Paths: ISO 15189 (Australia); In-house in-vitro diagnostic (IVD) (Europe); Laboratory Developed Test (LDT) (USA)
- PIQ using its expertise to adapt its sophisticated (mass spectrometry) tests for clinical use; by-passing need to create immunoassay (PromarkerD); set-up/train specialised Reference Laboratories
- Example: C2N Diagnostics successful launch of its Alzheimer's test

New, cost-effective routes to market

- Pandemic has changed the landscape: middle-man can now be cut out
- Allows PIQ and their partners to go direct to the patient
- Patients expect virtual testing - telehealth options - the health ecosystem has evolved to support this
- Will allow PIQ to obtain a far greater share of the revenue and have more control of strategy
- Minimal Capex and time required to execute on strategies: ~$100k's not millions and months not years

c2n.com/news-releases/cnnbspdiagnostics-releases-the-precivityad2-blood-test-for-clinical-care

The Problem: target populations for DKD, Endo & Eso

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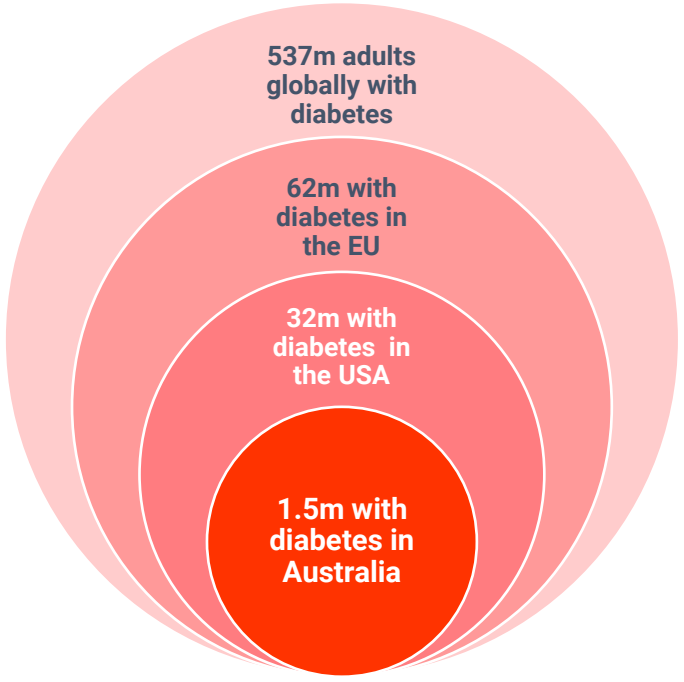
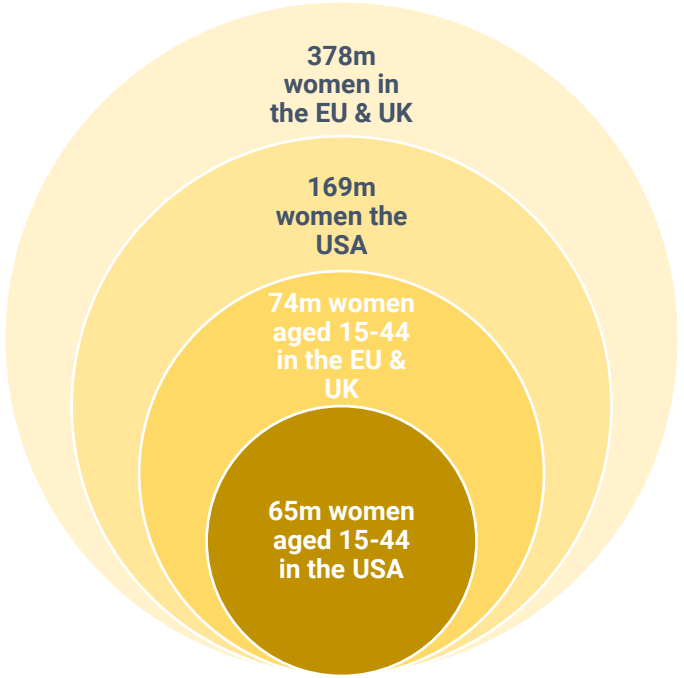
10.5% of global adult population have diabetes

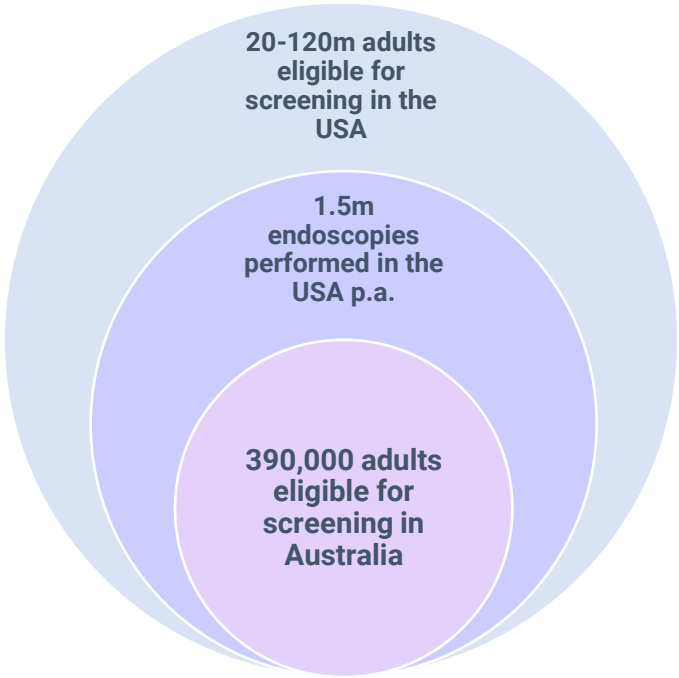


1 in 9 women have endometriosis



1-2% of western populations at risk of Esophageal Cancer

(Diagnosed by endoscopy with biopsy)



Sources:
www.statista.com/statistics/755225/population-of-europe-bygender/#:~:text=In%202023%2C%20the%20female%20population,male%20population%20of%20358.3%20million
International Diabetes Federation (IDF) Atlas 10th Edition 2021 [Age group 20-79 years]
www.medscape.com/viewarticle/990519?form=fpf
www.cancer.org.au/assets/pdf/9-august-2020
(European Commission)(StatisticsTimes)(ONS.gov).
Australian eligible adults screening determined as midpoint of 1-2% of Australian population of ~26m

The Solution: precision medicine targeting unmet needs

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PromarkerD

Diabetic Kidney Disease

- **1-in-3** with diabetes currently have chronic kidney disease
- **PromarkerD can predict onset of CKD** up to 4 years in advance – accuracy 86%
- Novel blood test taken yearly on average
- Targeting type 2 and type 1 diabetes
- New therapeutic treatments available – GLP-1 agonists, gliflozin class (SGLT-2s)
- **Targeting Australia Launch Q1 CY25**

PromarkerEndo

Endometriosis

- Potential **target is all** pre-menopausal women globally
- Currently **diagnosis takes average of 7-10 years**
- Standard of care for diagnosis is invasive surgery
- World-first blood test is ~90% accurate
- Significant community, Government and personal interest in the Endometriosis space
- **Targeting Australia Launch Q2 CY25**

PromarkerEso

Esophageal Cancer

- **1 in 20** cancer deaths worldwide due to esophageal cancer
- **5 year survival rate < 20%**
- Novel blood test is 94% accurate
- World-first blood test to screen for esophageal cancer
- Standard of care for diagnosis is endoscopy, which is costly and time consuming
- **Targeting Australia Launch Q1 CY25**

Go-to-Market Pathways

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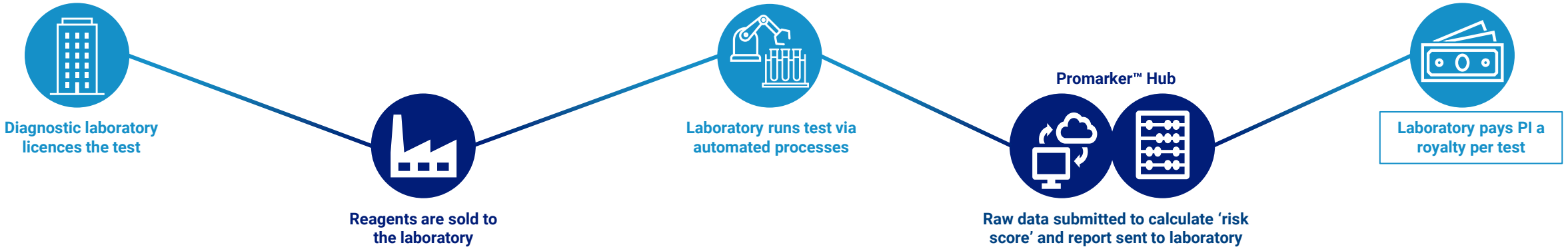
Proteomics International is pursuing a hybrid G2M strategy for its suite of novel diagnostic tests

Traditional licensing model



Direct to consumer/patient (DTC/DTP) and digital marketing pathway

Launch Strategy for DTP

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Establishing first sales via DTP builds product awareness and drives mainstream use and subsequent volume

Swiftly position each Promarker test as the key tool for patients & physicians

Step 1
Engage patients

- Direct to consumer advertising
- Patient advocacy groups
- Nurse practitioners & physicians via KOLs

Step 2
Motivate patients

- Understand their risk of disease
- Ease of access
- Telehealth consult for diagnosis

Step 3
Provide patient access

- Reduce barriers to obtaining a test
- Provide immediate fulfillment

Step 4
Drive and Grow sales

- Builds market awareness
- Focus on highly motivated patients' groups (e.g. T1D and endometriosis)
- Create a buzz about the tests
- Option to expand to new regions and partners

- Initial use via self-pay
- Existing PromarkerD PLA code & pricing (in US) provides engagement point for insurers
- Usage builds case for reimbursement of PromarkerEndo and PromarkerEso

DTP Significantly speeds up time to diagnoses, treatment & intervention

Awareness	Interest	Qualify and Pay	Tele-Consult	Blood-Draw	Reference Lab	Promarker Hub	Results & Intervention
Patient has medical concern and is offered telehealth solution	Patient clicks through media to landing page for relevant test	Patient is qualified and pays for test	Patient virtually meets with physician and online script provided	Patient is directed to nearest blood-draw centre for sample	Sample is sent to Reference Lab for analysis	Analysis is sent to Cloud-based Hub Results sent to consulting physician and patient	Depending on results, intervention may include: change of lifestyle; and/or therapeutic

minutes → **same day** → **48 Hrs** → **ongoing**

Promarker – Platform Technology

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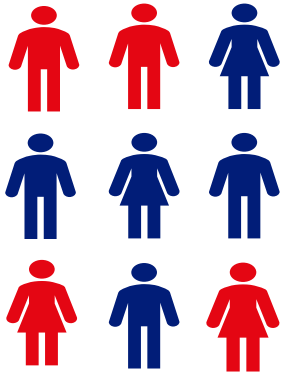
Promarker™ is a platform technology that can identify unique protein biomarkers ‘fingerprints’



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

Pipeline of Precision Diagnostics

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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

PromarkerD Global Rollout – Key Highlights

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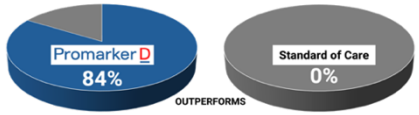
Intellectual Property	Patents granted in all major jurisdictions - PromarkerD Patent family & Trademark covers **72%** of the world's diabetes patients
Regulatory	**CE Mark** (EU) registration received for the PromarkerD Immunoassay IVD US sales utilising the Lab Developed Test (LDT) pathway via CLIA certified laboratories CE
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 **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

PromarkerD: Existing partnerships

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Proteomics International is focused on supporting its partners to achieve first sales in each jurisdiction

 **European Union** 61m+ T2 diabetics	• PromarkerD is CE Mark registered in Europe • Detailed market assessments completed	**Current Steps** • Establish independent Reference Laboratory
 **France, Italy, Spain +** 13.6m T2 diabetics	• **Appointed Growth Medics** as sales agency for Europe, targeting Netherlands, Belgium, Italy and Spain • **Eurobio Scientific licenced** to sell test in France	**Current Steps** • Engaging with potential Reference Labs & customers in designated markets • Assessing reimbursement pathways • Targeting further country partners
 **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*	**Current Steps** • Engaging with potential Reference Labs • Engaged with the NHS Supply Chain Tender • Targeting PromarkerD inclusion in the NICE guidelines
 **Puerto Rico, Chile & Dom Republic** 3m T2 diabetics	• **Licence with Omics Global Solutions** for immunoassay (Innovatio ND2): Puerto Rico, Dominican Republic, and Chile • Test registered with Ministry of Health • *First sales commenced*	**Current Steps** • Securing public reimbursement (Puerto Rico linked to CMS pricing and established PLA code) • Expanding uptake of the test through engagement with primary care physicians • *Exploring additional sales to neighbouring territories*

PromarkerD in the US: derisked & commercial ready

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Critical milestones have been achieved

Targeting the 32 million people with diabetes in the USA

Unique Proprietary Laboratory Analysis (PLA) code established

allows future crosswalk for T1D & T2D versions of test

Centres for Medicare & Medicaid Services (CMS) pricing established

$390.75

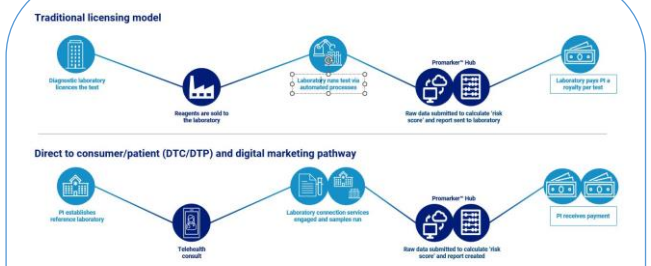
benchmark pricing for payors

Tech transfer to CLIA Certified Laboratory

automated systems already operating at PIQ

Clinical Advisory Board established

world class KOLs representing physicians, specialists, dieticians & nurse practitioners



Hybrid G2M strategy

targeting first sales 1H CY25

New PI reference laboratories will support roll-out of all Promarker tests
Processes built are accelerating path to market for PromarkerEndo & PromarkerEso

PromarkerEndo: Endometriosis

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World-first 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

- **Prototype test identified up to 90%** of patients with the disease (World Endometriosis Conference, May '23)
- **Patents pending** in all major jurisdictions
- Prototype test showed limitations in diagnosing symptomatic patients from minimal & mild endometriosis
- Advanced statistical modelling performed to **distinguish symptomatic patients from minimal & mild endometriosis**
- New clinical results **submitted for peer review publication**
- Further model optimisation being finalised using 'traffic light' system to improve test performance for clinical use
- Methodology (mass spectrometry) being **adapted for clinical launch**
- Discussions underway to establish test in reference laboratories in USA and Europe
- Proteomics International preparing **to launch PromarkerEndo in Australia** under ISO 15189 accreditation, targeting **Q2 CY25**

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=494; healthy individuals N=153; symptomatic controls N=254) (World Endometriosis Conference, May '23)
- *Clinical validation* - biomarker panel confirmed in independent patient cohort from St John of God Subiaco Hospital Gynaecological Cancer Research Group (N=241 patients) (Lorne Proteomics Symposium, Feb '24)
- *Clinical validation* - Collaboration ongoing with University of Oxford for international validation study (N=600 samples)

PromarkerEso: Esophageal Cancer

ASX: PIQ

World-first 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
   - 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)
- **Patents granted in Europe, China, Australia**; USA pending
- Model optimisation refined using 'traffic light' system to improve test performance for clinical use
- Latest **clinical validation results** presented at World Congress Esophageal Diseases, Sept '24
- Methodology (mass spectrometry) being **adapted for clinical launch**
- Discussions underway to establish test in reference laboratories in USA and Europe
- Proteomics International preparing **to launch PromarkerEso in Australia** under ISO 15189 accreditation, targeting **Q1 CY25**

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* – ongoing analysis of samples from Victoria Cancer Biobank to confirm clinical performance of the test (N=165)

Dx Pipeline: Oxidative Stress

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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** – 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*
  - ***Proof-of-concept study being finalised***
  - **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***

Potential spin-out opportunity:

- In discussions for third party investment




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

Timeline & Milestones

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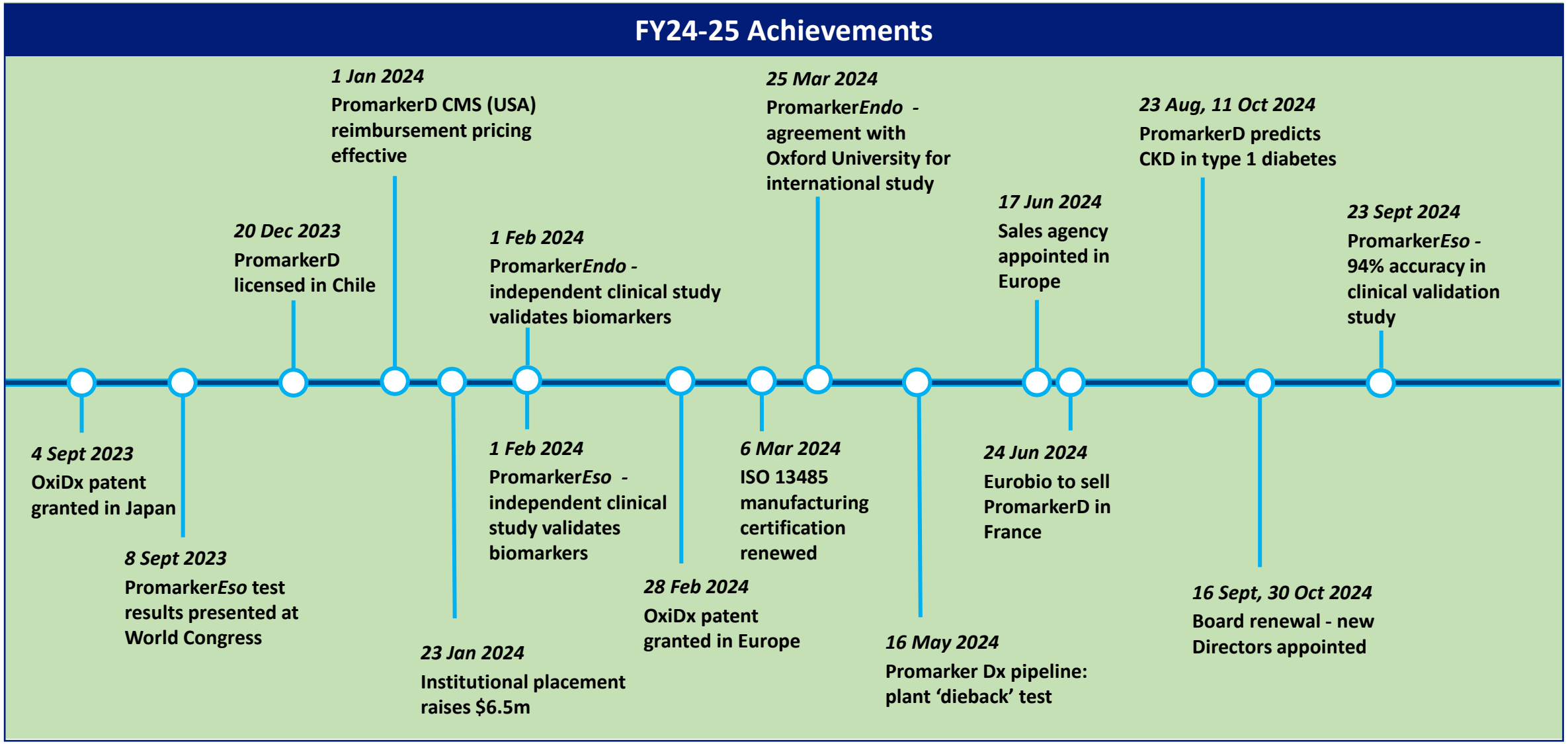

Multiple Value Drivers in FY25

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Exceptional Global Opportunity

- Disruptive, cutting-edge technology & proven in-house diagnostics platform
- PromarkerD test de-risked, patented, revenue ready
- PromarkerEndo and PromarkerEso tests nearing market entry
- Tests are scalable with high margins
- Whole of market appeal: pharma, clinical pathology labs, diagnostic platform developers, physicians and patients
- Vibrant corporate activity in the precision medicine, diagnostics and CRO (clinical trials) sectors

Potential Share Price Catalysts throughout FY25

Milestone	TARGET Qtr	Dec	Mar	Jun	Impact
Commercial					
First Sales PromarkerD in USA			■	■	Initiate pathway to significant revenues
PromarkerD launched in Australia			■		Drive global uptake and future revenue
PromarkerD launched in EU		■	■		Route to first sales in each country
PromarkerEndo launched in Australia				■	First sales
PromarkerEso launched in Australia			■		First sales
Clinical/Technical					
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
Regulatory/Reimbursement					
PromarkerD submissions (TGA, FDA)			■	■	Assist global roll-out
Endo 'FDA breakthrough' submission				■	Support US roll-out
Eso 'FDA breakthrough' submission			■		Support US roll-out

Contact

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Proteomics International

LABORATORIES LTD

Farewell

Dr John Dunlop

10th July 1942 - 15th December 2023

Inaugural Chair, Proteomics International
Director, Proteomics International, 2001 – 2018

On 15 December last year, Proteomics International and the Western Australian biotechnology industry lost one of its quiet achievers, Dr John Sutherland Richardson Dunlop. John was a serial entrepreneur and businessman, active across multiple sectors from biotechnology to mining and renewable energy for more than 50 years.

In 1982, John established Western Biotechnology with career-long colleagues Terry Sweet and Dr Bill Parker (both now also former directors of Proteomics International). The company, which was then the world's only producer of natural beta-carotene from algal lakes, was acquired by Hoffmann La Roche, and the plant is still operating today.

In 2001, John became the inaugural Chair of Proteomics International shortly after it was founded by Bill and Dr Richard Lipscombe. John served as a director throughout the company's formative years, only retiring from the board in 2018. John's guidance and steely Scottish pragmatism contributed enormously to Proteomics International's growth and ultimate ASX listing (as PIQ) in 2015.

John was one of life's true gentlemen, who wove his interests into a rich tapestry, from geologist (who also discovered one of the earliest forms of life on the planet in a rock formation in the Pilbara), to family man, rowing coach and Morris dancer. John told it like it was, underpinned with a bone-dry sense of humour. He will be greatly missed by all those who knew him.

Supplemental

Board of Directors

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Dr James Williams PhD (Melbourne), MBA (UWA), BSc, Hons (Aberdeen), GAICD, Non-Executive Director & Chair elect

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.

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.

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 Chair (standing down AGM Nov 24)

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.

Roger Moore R (Denmark), BPharm (U.Syd), Non-Executive Director (retiring AGM Nov 24)

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.

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).

Promarker D

PROACTIVELY CHANGING RENAL HEALTHCARE

A simple blood test for predicting diabetic kidney disease

PromarkerD: World Class Advisory Board

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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)

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

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

Problem and Solution – Diabetic Kidney Disease

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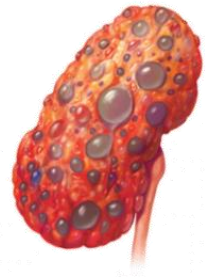
The Problem

- **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**

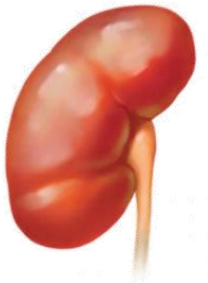


Diseased Kidney

Solution

PromarkerD

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



Healthy Kidney

International Diabetes Federation 2021
US Renal Data System 2020

PromarkerD - Patented in all Major Markets

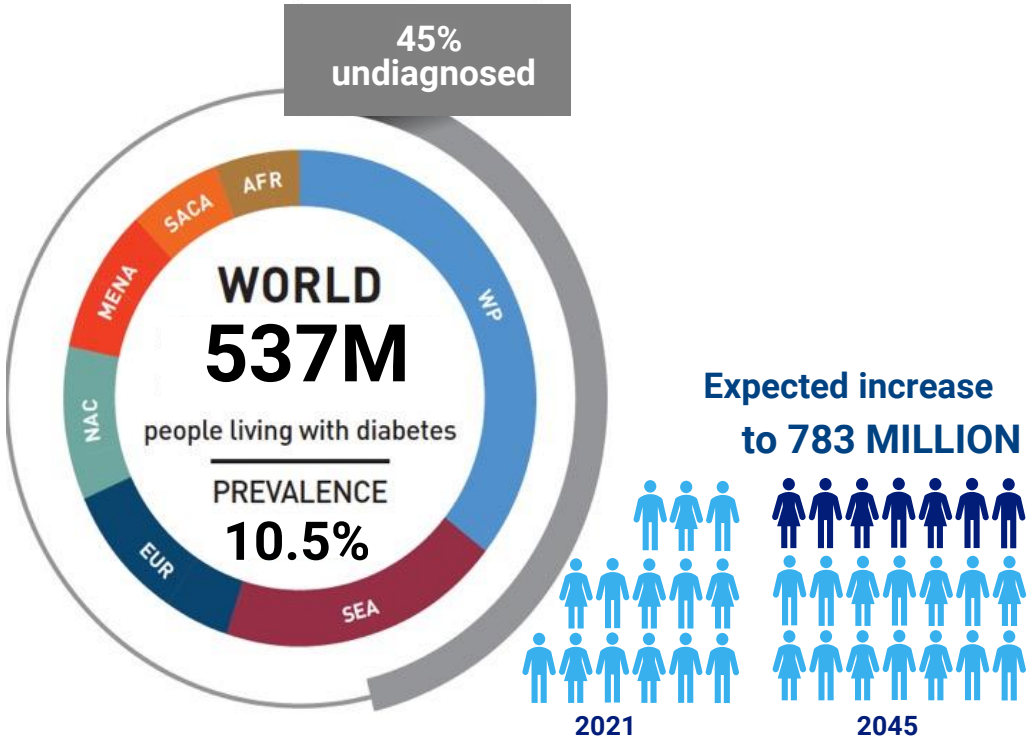
ASX: PIQ

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

Patent family & Trademark covers 72% of world's diabetics[1]

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
4. USA patent further extended to cover method for identifying drugs for abnormal kidney function using one of the PromarkerD biomarkers (CD5L)

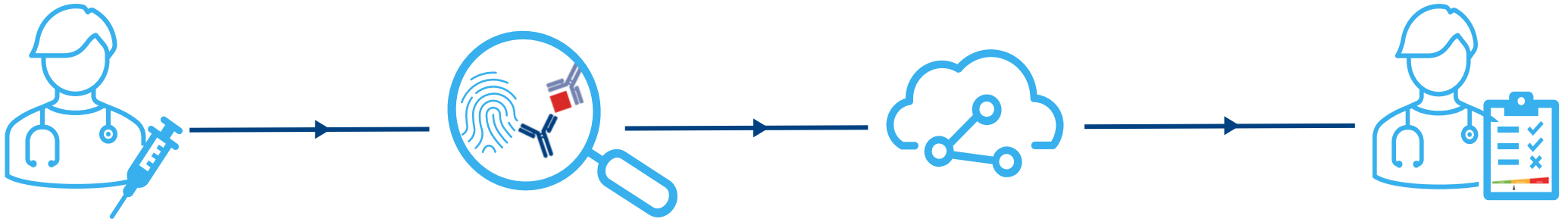


Market assumptions

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

PromarkerD – Simple Integration & Use

ASX: PIQ



Blood sample drawn

Sample is drawn at clinic or pathology laboratory

Biomarkers analysed

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

Results generated by PromarkerD Hub software

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

Results and intervention plan delivered

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

ASX: PIQ

How PromarkerD results are delivered

Prognostic **16%** indicates a **moderate** risk of decline in kidney function*

Risk Score	Intervention	Testing Regimen
Low Risk	• Standard diabetes management	**Test Annually**
Moderate Risk	• More frequent monitoring • Optimisation of lifestyle • Review of glycemic targets and management • Review non-glycemic risk factors • Avoidance of potentially nephrotoxic drugs	**Test every 6 months**
High Risk	• Very close monitoring • Intensive management strategies based on those for 'Moderate risk' above • Utilisation of therapeutic drugs	**Test every 3 months**

*as defined by incident diabetic kidney disease (eGFR <60ml/min/1.73m^2) in the next four years. Note: if eGFR level at the time of the test is already <60ml/min/1.73m^2, then the risk of a further decline in kidney function is defined as an eGFR decline >30% in the next four years

PromarkerD: Clinical Utility & Decision Impact

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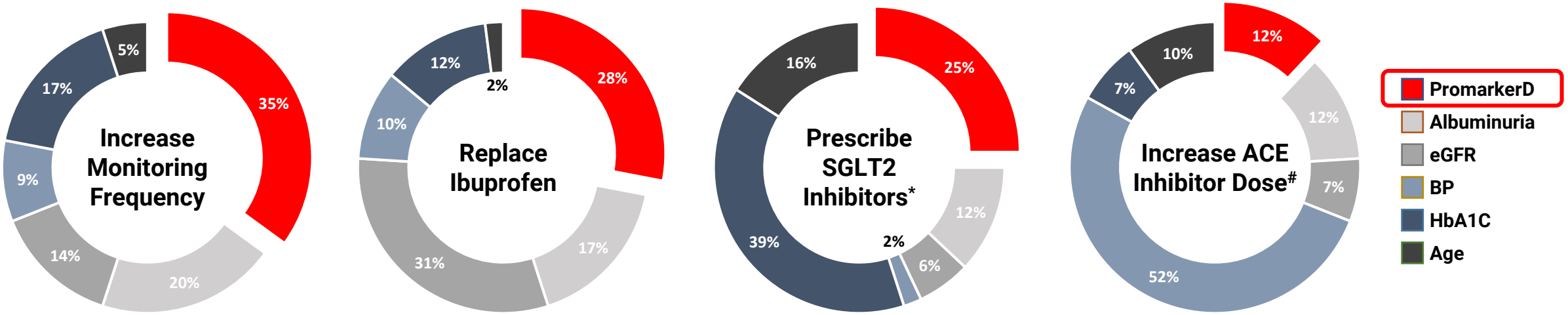
Launch strategy supported by engagement with KOLs and primary care physicians

Published Research[1] indicates physicians would use PromarkerD to inform patient treatment decisions

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



* SGLT2-inhibitor class of medications are already widely used for the treatment of diabetes, and now also indicated for cardiovascular disease and DKD.
# ACE Inhibitor class of medications are commonly used for the treatment of high blood pressure and heart failure.

1. *PLOS ONE. 2022*

PromarkerD: Precision in the Clinic

ASX: PIQ

Peer Reviewed

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

10+ Peer Reviewed Publications

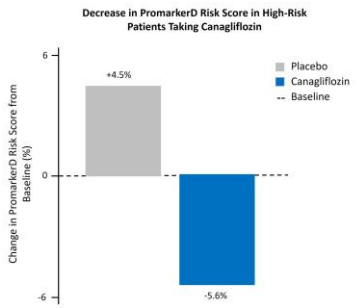
World leading results:

- 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 ($P = 1.3x10^{-104}$)

[J. Clin. Med. (2020)]

- PromarkerD **high-risk patients show greatest benefit** from early use of SGLT2-inhibitor

[J. Clin. Med. (2023)]



Physician Support

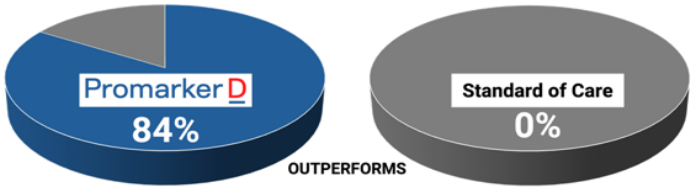
Survey of 400 Endocrinologists & Primary Care Physicians (US based)

- **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: Precision Medicine

ASX: PIQ

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, canaglifozin, 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**

Kidney Research UK. Kidney disease: A UK public health emergency;
Kidney Health Australia. Deloitte Access Economics report: Changing the chronic kidney disease landscape
Investor.lilly.com/news-releases; www.novonordisk.com/news-and-media

PromarkerD: Key Publications

ASX: PIQ

Prognostic Validation for Type 1 Diabetes	Davis TME, et al. Application of a validated prognostic protein biomarker test for renal decline in type 2 diabetes to type 1 diabetes: The Fremantle Diabetes Study Phase II. ADC 2024.
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. 2023.
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. 2022.
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 Diabetes. Poster presented at ASN Kidney Week. 2021.
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. 2020.
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. 2022.
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. 2019.
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. 2017.
Diagnostic Study	Bringans SD, et al. Comprehensive Mass Spectrometry Based Biomarker Discovery and Validation Platform as Applied to Diabetic Kidney Disease. EuPA Open Proteomics. 2017.
Cross-platform Validation	Bringans SD, et al. The New and the Old: Platform Cross-Validation of Immunoaffinity MASS Spectrometry versus ELISA for PromarkerD, a Predictive Test for Diabetic Kidney Disease. Proteomes. 2020.