

## Disclaimer



This Presentation is provided by Proteomics International Laboratories Ltd (Proteomics International, Proteomics, the Company, ASX: PIQ).

You should not rely upon anything in this presentation and/or any information obtained from the Company, its Directors or their associates in deciding whether or not to seek to purchase the shares of the Company. This is not an offer to subscribe for securities in the Company.

The Presentation may contain quantitative statements of anticipated future performance such as projections, forecasts, calculations, forward-looking statements or estimates all of which are based on certain assumptions (Forward Looking Statements). The Forward Looking Statements may involve subjective judgements and are based on a large number of assumptions and are subject to significant uncertainties and contingencies, many of which are outside the control of the Company and may not prove to be correct.

No representation or warranty is made that any Forward Looking Statements will be achieved, or occur, or that the assumptions upon which they are based are reasonable or the calculations from which they have been derived are correct. Actual future events may vary significantly from the Forward Looking Statements. Each Recipient should undertake their own independent review of the Forward Looking Statements, including the assumptions on which they are based and the financial calculations from which they are derived.

### **Proteomics International Laboratories Ltd**



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

### Diagnostics (Dx)

#### **PromarkerD**

- Predictive test for early identification of diabetic kidney disease (DKD)
- In market, cost-effective, easy to use, patented technology

Strong pipeline of novel tests in development – Endometriosis, Asthma & COPD, Oesophageal cancer, Diabetic retinopathy, Oxidative Stress

#### **Bioanalytical Services**

- Growing demand from industry for specialised analytics
  - Thriving sectors of pharmacokinetic (PK) testing and biosimilars
- State-of-the-art capabilities with >\$5m invested in cutting-edge facility
- Revenue partially offsets the cash burn from R&D and product development

#### **Financial & Corporate**

- ASX listed; 29 staff; headquartered on QEII Medical Campus, Perth, WA
- Raised \$8m (gross) in heavily oversubscribed placement (Aug 22)
- Manufacturing (\$0.4m; May 22) and Dx facility (\$0.85m; Oct 22) funding
- Implementing expansion strategies to accelerate growth

Corporate Snapshot - 30/01/2023	
ASX code	PIQ
Share Price	A\$1.125
Shares on issue (+5.7m options)	118m
Market Capitalisation	A\$133m
Revenue & other income – FY22	A\$3.4m
Cash (31 Dec '22) + \$1.86m options exercised Jan '23	\$6.8m
Net cash burn – FY22	A\$3.5m
Directors Shareholding	18%

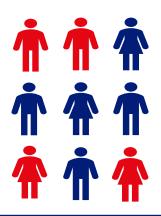


# Promarker - Platform Technology





Promarker<sup>™</sup> is a platform technology that can identify unique protein biomarkers 'fingerprints'

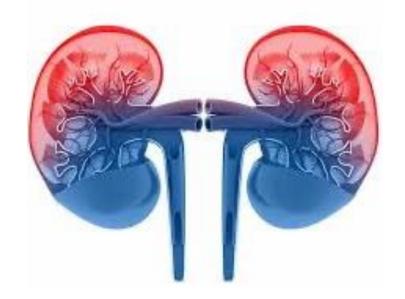


The platform identifies and links the unique protein biomarkers to specific diseases, enabling Proteomics International to create novel diagnostic tests

# Promarker D

PROACTIVELY CHANGING RENAL HEALTHCARE

A simple blood test for predicting diabetic kidney disease



### **Problem and Solution**





#### 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 = U\$\$130 Bn per year in USA alone



Solution

### **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



International Diabetes Federation 2021 US Renal Data System 2020

# PromarkerD is Revenue Ready

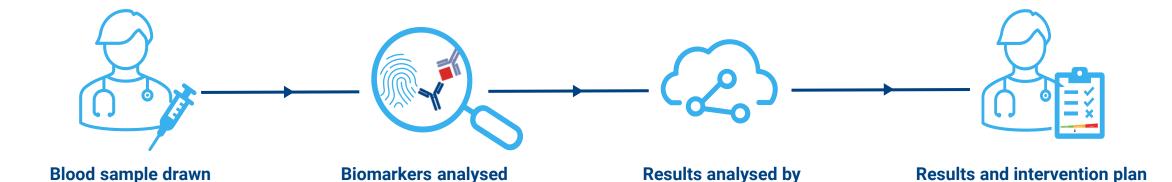


Kev	hiah	liahts	towards	s a al	lobal	roll-out	t
		<i>– – –</i>		J			

<b>Enormous Market</b>	537m adults have diabetes globally: 1-in-3 currently have diabetic kidney disease (DKD)
High Statistical Performance	Peer reviewed publications – Clinical & analytical validity proven (Sensitivity 86%); PromarkerD significantly outperforms current standard of care
Big Pharma Collaboration	Janssen (J&J) – Global multi-centre clinical study - assessed PromarkerD against drug treatment
Therapeutic Treatments Available	SGLT2-inhibitor class drug (canagliflozin) improves PromarkerD risk scores – potential as Complementary Diagnostic (CDx) [drug class already used for type 2 diabetes & now approved as new treatment for DKD]
Simple Technology Platform - PromarkerD Immunoassay	Clinical pathology laboratories can easily introduce the PromarkerD immunoassay as an IVD kit or LDT
Regulatory Approvals	CE Mark (Europe) registration received for the PromarkerD Immunoassay; US sales utilising the Lab Developed Test (LDT) pathway via CLIA certified laboratories; Secured ISO 13485 certification for the manufacture of medical devices
Regulatory Approvals - ongoing	Engaging with international partners and national regulators; application pending with Australian TGA
Manufacturing scale-up	Technology transferred to ISO 13485 certified EU manufacturer; pilot batches of kit & assay completed
First Sales	Sales initiated in Central America; Partnership with Sonic Healthcare USA announced for US mainland
Reimbursement	USA: Secured unique PLA reimbursement code & progressing towards payment coverage; Engaged with NHS (UK) and MSAC (Australia); Economic Health Benefit & Clinical Utility demonstrated

# PromarkerD - Simple Integration & Utilisation





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) Cloud based algorithm, the "PromarkerD Hub" calculates the patient's kidney disease risk score

PromarkerD Hub software

Employs a traffic light system for optimal performance, classifies patients as:

- low risk
- moderate risk
- high risk

Clinician delivers results to patient

delivered

Depending on results, intervention may include:

- change of lifestyle; and/or
  - therapeutic drugs

# PromarkerD Market Opportunity

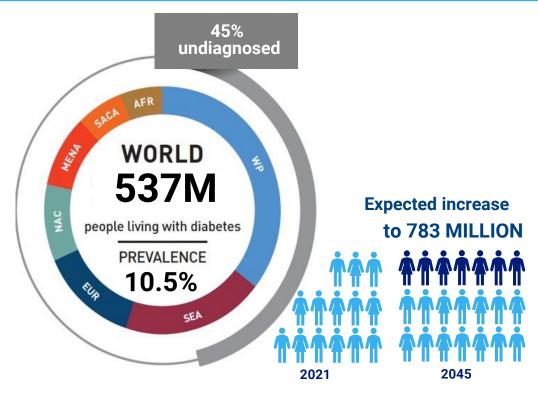


### **Diabetes incidence and Patent portfolio**

Country	Patent/Application No	Patent Status	No. Diabetics <sup>1</sup>
Australia	2011305050	Granted	1,491,800
Brazil	BR112013006740	Granted	15,733,600
Canada	2811654	Granted	2,974,000
China	ZL201180053583.9	Granted	140,869,600
Europe <sup>2,3</sup>	3151012	Granted	61,425,100
Hong Kong	18115912.3	Granted	686,000
India	3012/DELNP/2013	Granted	74,194,700
Indonesia	W00 2013 01585	Granted	19,465,100
Japan	2013-528474	Granted	11,005,000
Russia	2596486	Granted	7,392,100
Singapore	188527	Granted	711,800
USA <sup>2,4</sup>	US 9,146,243	Granted	32,215,300

#### ~340 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 use of the test for **any form of kidney disease** (NB further studies are required to prove efficacy of PromarkerD for applications beyond DKD)
- 3. Covers France, Germany, Italy, Spain, Turkey and the United Kingdom, which cumulatively have 32.8m adults with diabetes
- 4. USA patent further extended to cover **method for identifying drugs for abnormal kidney function** using one of the PromarkerD biomarkers (CD5L)

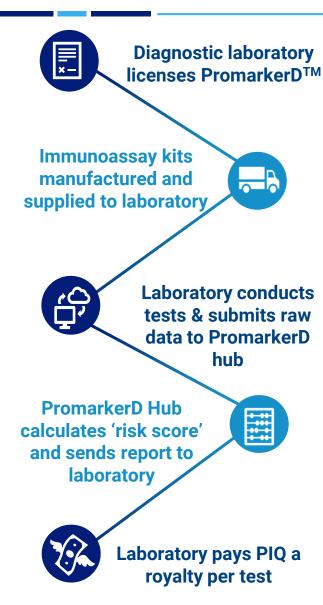


### **Market assumptions**

- Patent family & Trademark covers 72% of world's diabetics<sup>1</sup>
- Test is performed once per year per patient on average
- Test price minimum of US\$150 [based on stakeholder engagement responses in a market access study]
- Standard industry **royalty rates range from 5-15%**

# PromarkerD - Route to US and Global Markets





### **Key Markets**

#### **United States**

- Binding Letter of Intent signed with Sonic Healthcare USA
- LOI details terms and conditions to market and sell PromarkerD in the USA
- PromarkerD test now listed on Sonic Reference Laboratory (USA) website
- CPT PLA reimbursement code approved Jan 2023

#### **RoW**

- Detailed market assessments completed
- Actively targeting potential partners in key jurisdictions

APACOR

### Completed Licensing Transactions

#### **Britain**

- Licence with Apacor Ltd for immunoassay test
- 4.8m type 2 diabetics (7%)
- Test registered with Medicines
   & Healthcare products
   Regulatory Agency
- National Institute for Health & Care Excellence (NICE) Medtech Innovation Briefing "NICE Advice" published

#### **Central America**

- Licence with Omics Global Solutions for immunoassay (Innovatio ND2) in Puerto Rico & Dominican Republic
- 1.3m type 2 diabetics (9%)
- Test registered with Ministry of Health
- First sales commenced



### SONIC REFERENCE LABORATORY

PromarkerD Diabetic Kidney Disease Risk Assessment

Early detection can significantly help prevent

#### Israel

- Licence with Zotal Ltd for immunoassay test
- 0.6m type 2 diabetics (12%)
- Product registration on-hold pending first sales globally

ZOTAL

# Diagnostics Pipeline



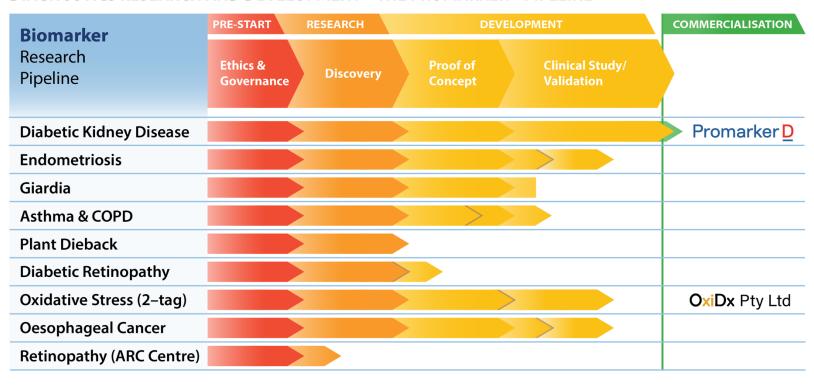
# The Promarker™ Research Pipeline & Timeline



#### **Further Global Potential in New Markets**

- Employs the Promarker™ technology platform to develop 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

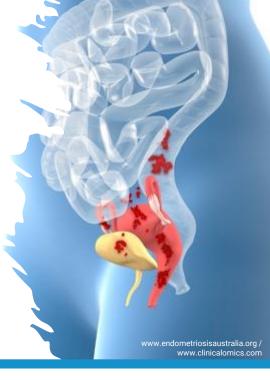


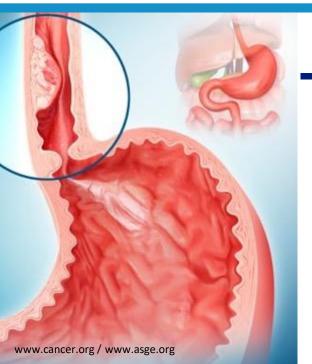
# In Development: Endometriosis

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

#### **Promarker<sup>TM</sup> for Endometriosis**

- Clinical validation study identified up to 78 in 100 people with the disease (Fertility Society ANZ, July '22)
- Collaboration with Royal Women's Hospital & University of Melbourne analysed 857 samples; additional statistical modelling ongoing to improve test accuracy
- Biomarkers identified via the Promarker<sup>™</sup> platform offer potential world-first blood test for endometriosis





# In Development: Oesophageal Cancer

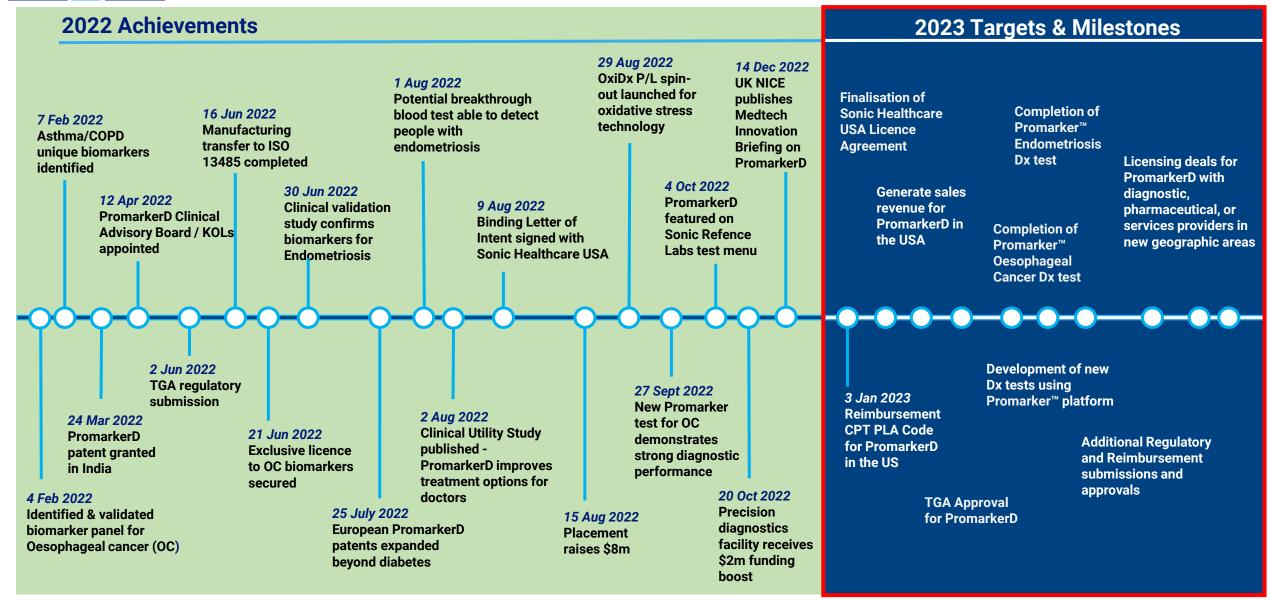
- 1 in 20 cancer deaths worldwide due to oesophageal cancer five year survival rate < 20%</li>
- Currently diagnosis requires a specialist endoscopy procedure; treating the disease cost \$2.9bn in USA in 2018
- Test targets both oesophageal adenocarcinoma and patients with pre-malignant condition Barrett's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

### **Promarker**<sup>TM</sup> for Oesophageal Cancer and Barrett's esophagus

- Prototype test identified up to 90 in 100 people with the disease (World Congress for Esophageal Diseases, Sept '22)
- Collaboration with QIMR Berghofer Medical Research Institute analysed 302 samples; additional statistical modelling ongoing to improve test accuracy
- Biomarkers identified via the Promarker™ platform offer potential world-first blood test for oesophageal cancer

## **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 CY23** 

Milestone	1H CY23	2H CY23	Impact
PromarkerD			
Licensing Deals			Execution of Sonic Healthcare USA licence; Drive global uptake and future revenue
First Sales in Key Markets			Drive revenue
Reimbursement – US payor coverage			Adoption of CPT PLA code by payors enables broad adoption of test
Regulatory Submissions, Approvals & Reimbursement RoW			Build user confidence in product & assist in global roll-out
Promarker™			
Endometriosis Dx			New first-in-class diagnostic test
Oesophageal Cancer Dx			New first-in-class diagnostic test
Diagnostics Pipeline Updates			New IP (validation & proof of concept results)
Analytical Services			
New Contracts			Off-set cash burn & engages potential future partners

# Peer Comparison



		Stock Code	e Company Focus	Market Capitalisation	Share Price	FY22 Revenue	FY22 Net Profit/Loss
Proteomics International LABORATORIES LTD	Proteomics International Laboratories	PIQ.ASX	Predictive blood test measuring novel protein biomarkers for DKD; simple, cost effective, commercial ready. Pipeline of novel diagnostic tests in development for chronic diseases.	A\$133m	A\$1.125	A\$1.7m	A\$4.9m loss
::INOVIQ	Innoviq Ltd	IIQ.ASX	Early stage in-licensed IP for various cancer diagnostics.	<b>A</b> \$60m	A\$0.65	A\$0.3m	A\$18m loss
<b>Lucid</b> diagnostics	Lucid Diagnostics Inc	LUCD.US	Cancer prevention medical diagnostics company with a DNA test (via LDT) for oesophageal cancer.	~A\$70.5m	US\$1.28	~A\$0.4m (9 months to 30 Sep 22)	~A57m loss (9 months to 30 Sep 22)
renal)tix <b>a</b> l	Renalytix Al	RENX.LSE RNLX.US	DKD test based on AI and a combination of predictive blood-based biomarkers, genetic factors and electronic health records. Expensive (US\$950 per test), non-mass market.	~A\$175m	GBP1.35	~A\$4m (FY 22)	~A\$78m loss (FY 22)
RHYTHM BIOSCIENCES	Rhythm Biosciences	RHY.ASX	Pre-commercialisation proteomics derived diagnostic test for colon cancer licensed from CSIRO.	A\$217m	A\$1.00	Nil	A\$8.8m loss
TELIX	Telix Pharmaceuticals	TLX.ASX	Recent commercial launch of first diagnostic product for cancer imaging in the USA. Pipeline of diagnostic and therapeutic products based on molecularly targeted radiation in development	A\$2.25Bn	A\$7.12	A\$130m (6 months to 30 Dec 2022)	~A\$10m loss (6 months to 30 Dec 2022)

## Contact



### **Dr Richard Lipscombe**

### **Managing Director**

T: +61 8 9389 1992

E: enquiries@proteomicsinternational.com

www.proteomicsinternational.com



### **Kyle Moss**

#### **Corporate Advisor**

**Euroz Hartleys** 

T: +61 9488 1400

E: kmoss@eurozhartleys.com

### **Dirk van Dissel**

### **Investor Relations & Corporate Advisor**

**Candour Advisory** 

T: +61 408 326 367

E: dirk@candouradvisory.com.au

**ASX:PIQ** 

# Supplemental



### **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).

# PromarkerD - Results & Intervention

#### How PromarkerD results are delivered

	LOW RISK	MODERATE RISK		HIGH RISK	
RISK SCORE % 0	10	<b>A</b>	20		100

**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	<ul> <li>More frequent monitoring</li> <li>Optimisation of lifestyle</li> <li>Review of glycemic targets and management</li> <li>Review non-glycemic risk factors</li> <li>Avoidance of potentially nephrotoxic drugs</li> </ul>	Test every 6 months	
High Risk	<ul> <li>Very close monitoring</li> <li>Intensive management strategies based on those for 'Moderate risk' above</li> <li>Utilisation of therapeutic drugs</li> </ul>	Test every 3 months	

<sup>\*</sup>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 <60ml/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



### PromarkerD significantly enhances diabetic kidney disease diagnosis and management

[ASN (Nov 2021)]

	Peer reviewed	PromarkerD tested on <b>over 5,000 patients</b> in 4-year clinical studies		
<b>%</b>	High Accuracy	PromarkerD <b>predicted 86</b> % of otherwise healthy patients with T2D who went on to develop chronic kidney disease ('incident DKD') within 4 yrs [Diabetes Care (2017), J Diabetes Complications (2019)]		
janssen <b>T</b>	International validation	Janssen (J&J) collaboration stage 1 – global clinical study - PromarkerD predicted 'incident DKD' in the completed CANVAS clinical trial; high-risk patients <b>13.5 times more likely</b> than low-risk to develop DKD (P = $1.3x10^{-104}$ ) [J Clinical Medicine (2020)]		
janssen <b>J</b>	New DKD treatment options identified	Janssen collaboration stage 2 – assessed the drug treatment effect of canagliflozin versus placebo on PromarkerD risk scores in the completed CANVAS 4 year clinical trial:  **Aim: Do 'at-risk' patients continue to decline, or stabilize, or recover?  **Results: Patients predicted at baseline by PromarkerD to be high-risk for developing DKD -  ** Treated with canagliflozin had significantly lower scores at Year 3 (Δ score: -5.6%; p<0.001)  ** Patients on placebo remained high (Δ score: 3.2%; p=0.17) (Time*TRT p=0.002) [ADC (Aug 2021)]  **Conclusion: PromarkerD can identify 'at-risk' patients who are asymptomatic for DKD, with canagliflozin offering a potential treatment that can improve their renal risk profile		
<b>(</b>	Outperforms Standard of Care	PromarkerD compared to standard of care tests (eGFR and ACR) for predicting DKD.  Community based study of patients with T2D (N=857);  Patients tested for existing DKD at baseline: 497 had normal kidney function, but of these 9% (N=45) developed 'incident DKD' in the next 4 years – all were missed by standard of care tests whilst PromarkerD identified 84% (N=38) of these		