

Proteomics International

LABORATORIES LTD

**ASX Release
4 November 2022**

ASX code: PIQ

Investor Presentation to the Emerging ASX Gems Conference

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) is pleased to release a copy of the presentation to be provided by Managing Director Dr Richard Lipscombe to attendees of The Capital Network's Emerging ASX Gems Conference being live streamed today:

www.eventbrite.com.au/e/the-capital-networks-emerging-asx-gems-tickets-445575998807

Authorised by the Board Proteomics International Laboratories Ltd (ASX.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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Investor Presentation

Emerging ASX Gems Conference

4 November 2022

Dr. Richard Lipscombe

Managing Director

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

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Proteomics International Laboratories Ltd



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

Diagnostics

PromarkerD

- Predictive test for early identification of diabetic kidney disease (DKD)
- Revenue ready, 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 >\$4m invested in cutting-edge facility
- Revenue partially offsets the cash burn from R&D and product development

Financial & Corporate

- Raised \$8m (gross) in heavily oversubscribed placement (Aug 22)
- R&D Tax Rebate of \$1.7m received (Oct 22)
- \$0.4m for manufacturing - Medical Research Future Fund initiative (May 22)
- Implementing expansion strategies to accelerate growth

Corporate Snapshot – 31/10/2022

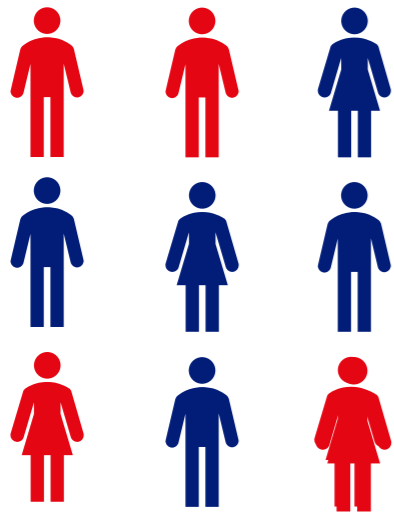
ASX code	PIQ
Share Price	A\$0.915
Shares on issue (+8.4m options)	115m
Market Capitalisation	A\$105m
Revenue & other income – FY22	A\$3.4m
Cash (30 Sept '22 + \$1.7m R&D received Q4 CY22)	\$6.4m
Net cash burn – FY22	A\$3.5m
Directors Shareholding	~18%



Promarker – Platform Technology



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

Promarker D

WE'RE CHANGING LIVES

A new blood test for predicting diabetic kidney disease





The Problem

- **537 millions diabetics globally**
- **1-in-3 diabetic** adults 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



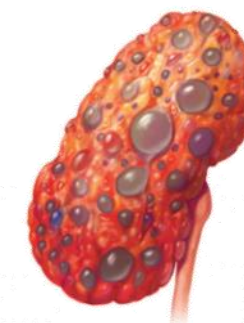
Roadblock



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

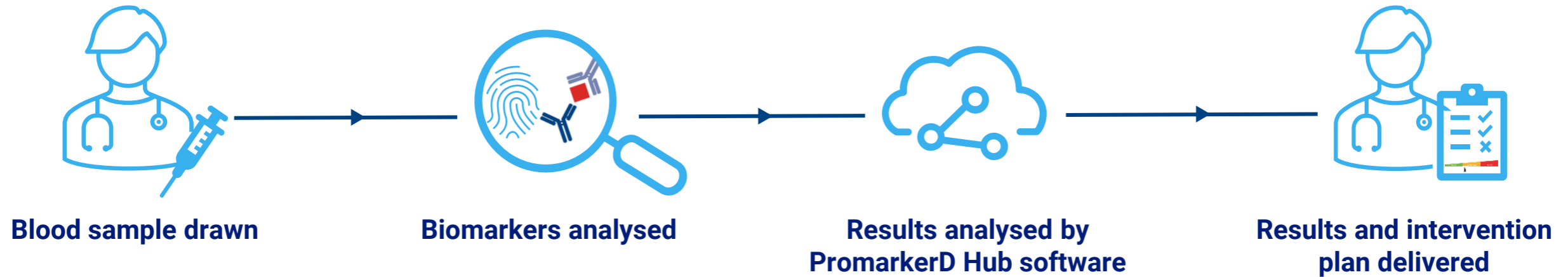
Promarker **D**

- 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



Healthy Kidney

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

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

PromarkerD – Route To Market

Diagnostic company / laboratory
license PromarkerD™



Laboratory conducts tests & submits raw
data to PromarkerD hub



Laboratory pays PIQ a royalty per
test



Immunoassay kits
manufactured and supplied
to laboratory



PromarkerD Hub calculates 'risk score'
and sends report to laboratory

Completed Licensing Transactions

Great Britain

- Licence with Apacor Ltd for immunoassay test
- 4.8m type 2 diabetics (7%)
- Test registered with Medicines & Healthcare products Regulatory Agency



Israel

- Licence with Zotal Ltd for immunoassay test
- 0.6m type 2 diabetics (12%)
- Preparing for launch in CY23 following completion of ISO 13485 manufacturing



PromarkerD Diabetic Kidney Disease Risk Assessment

Early detection can significantly help prevent serious kidney damage.

Targeted Licensing Transactions

United States

- Binding letter of Intent signed with Sonic Healthcare USA

RoW

- Actively targeting potential partners in key global jurisdictions

Diagnostics Pipeline

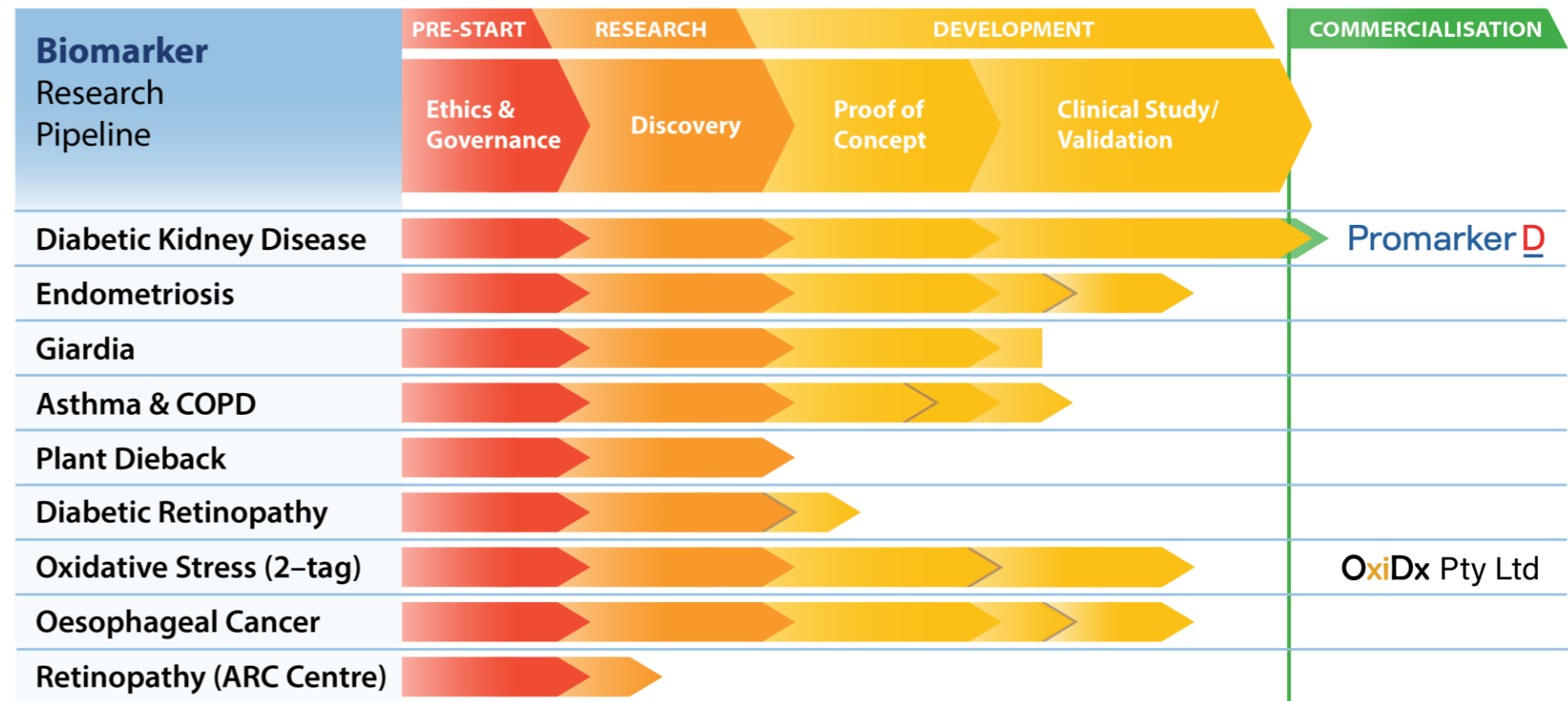
The Promarker™ Research Pipeline & Timeline



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

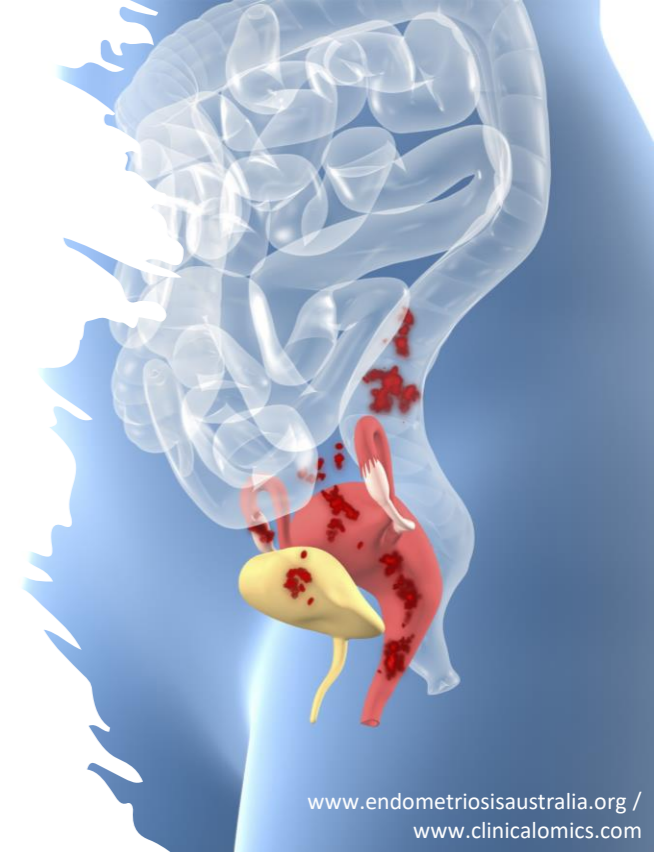


In Development: Endometriosis

- 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™ 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™ platform offer **potential world-first blood test for endometriosis**



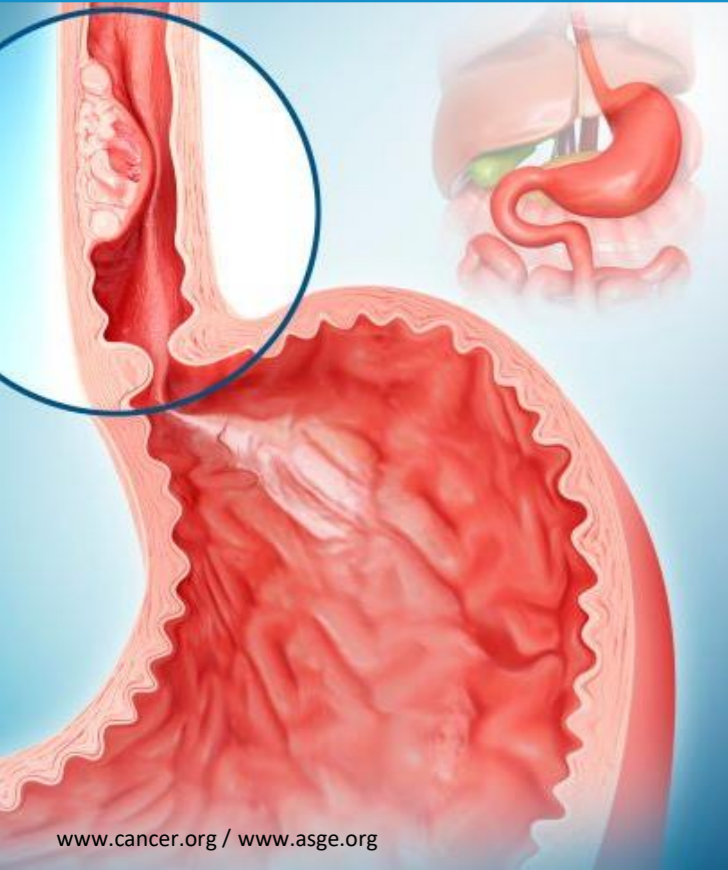
www.endometriosisaustralia.org/
www.clinicalomics.com

In Development: Oesophageal Cancer

- **1 in 20 cancer deaths worldwide** due to oesophageal cancer – **five year survival rate < 20%**
- 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™ 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**



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 FY23

Milestone	Dec Qtr '22	1H CY23	Impact
PromarkerD			
Licensing Deals			Execution of Sonic Healthcare USA licence. Drive global uptake and future revenue
First Sales			Drive revenue
Reimbursement - US			CPT PLA code outcome & Payor coverage
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

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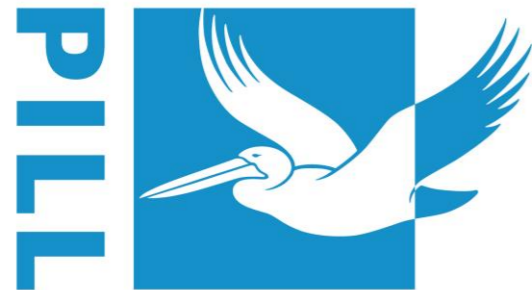
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Peer Comparison



	Stock Code	Company Focus	Market Capitalisation	Share Price	FY22 Revenue	FY22 Net Profit/Loss
<p>Proteomics International Laboratories</p>	PIQ.ASX	Predictive blood test for Diabetic Kidney Disease; simple, cost effective, pending launch in USA. Pipeline of novel proteomics derived diagnostic tests in development for chronic diseases.	A\$109m	A\$0.96	A\$1.5m	A\$4.9m loss
<p>Innoviq Ltd</p>	IIQ.ASX	Early stage in-licensed IP for various cancer diagnostics.	A\$52m	A\$0.52	A\$0.3m	A\$18.2m loss
<p>Lucid Diagnostics Inc</p>	LUCD.US	Commercial-stage, cancer prevention medical diagnostics company with a DNA test (via LDT) for oesophageal cancer.	~A\$103m	US\$1.71	~A\$0.3m (6 months to 30 Jun 22)	~A40m (6 months to 30 Jun 22)
<p>Renalytix AI</p>	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\$69m	52.5p	~A\$2.1m (6 months to 31 Dec 2021)	~A\$43m loss (6 months to 31 Dec 2021)
<p>Rhythm Biosciences</p>	RHY.ASX	Pre-commercialisation proteomics derived diagnostic test for colon cancer licensed from CSIRO.	A\$278m	A\$1.30	Nil	A\$8.8m loss
<p>Telix Pharmaceuticals</p>	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\$1.66Bn	A\$5.31	A\$24m (6 months to 30 Jun 2022)	A\$71m loss (6 months to 30 Jun 2022)

Source: Company filings. Market data as at 10 August 2022, exchange rates of GBP:AUD 1.75 and USD:AUD 1.57

Board of Directors



Neville Gardiner BBus (Accounting and Business Law) (Curtin), CA, MAICD, 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 is Revenue Ready

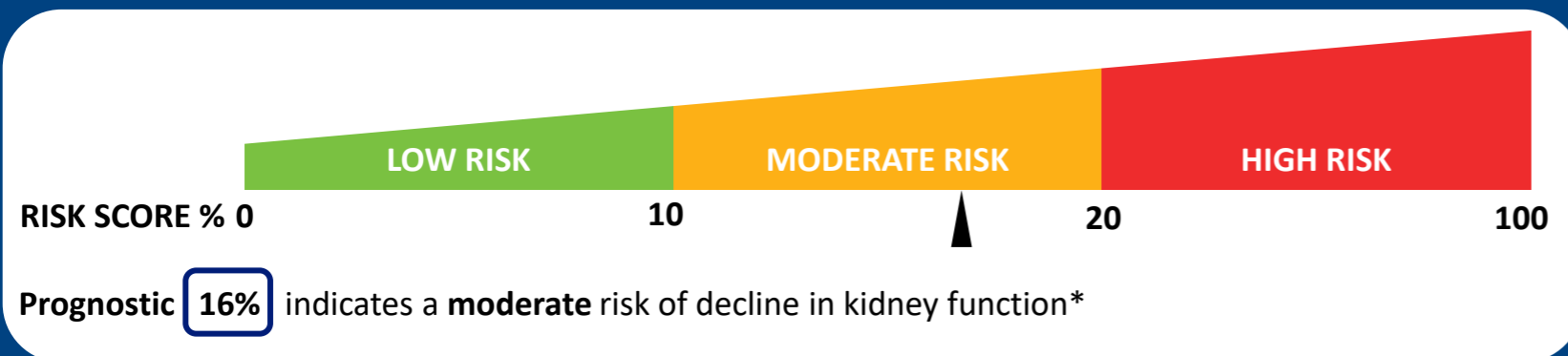


The PromarkerD predictive test is poised to roll-out in markets globally

Enormous Market	✓	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	✓	 (J&J) – global multi-centre clinical study - assessing PromarkerD vs treatment options
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; Secured ISO 13485 certification for the manufacture of medical devices
Manufacturing scale-up	✓	Technology transfer completed to ISO 13485 certified kit & assay manufacture
Reimbursement	●	Identified pathway to obtain a unique reimbursement code & payment coverage in the USA; engaged with NHS (UK) and MSAC (Australia): Economic Health Benefit & Clinical Utility demonstrated
Regulatory Approvals - ongoing	●	Engaging with partners and national regulators [US sales to utilise the Lab Developed Test (LDT) pathway with CLIA laboratories, prior to FDA approval]
Generate Sales Revenue	●	Partnership with Sonic Healthcare USA announced for PromarkerD immunoassay – initial sales pending

PromarkerD – Results & Intervention

How PromarkerD™ results are delivered



Risk Score	Intervention	Testing Regimen
Low Risk	<ul style="list-style-type: none"> Standard diabetes management 	Test Annually
Moderate Risk	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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/1.73m²) 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



Peer reviewed

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



High Accuracy

PromarkerD **predicted 86%** of otherwise healthy diabetics who went on to develop chronic kidney disease ('incident DKD') within 4 yrs [Diabetes Care (2017), J Diabetes Complications (2019)]



International validation

Janssen (J&J) collaboration stage 1 – global clinical study - PromarkerD predicted 'incident DKD' in the completed CANVAS clinical trial; high-risk patients **13.5 times more likely** than low-risk to develop DKD ($P = 1.3 \times 10^{-104}$) [J Clinical Medicine (2020)]



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)]

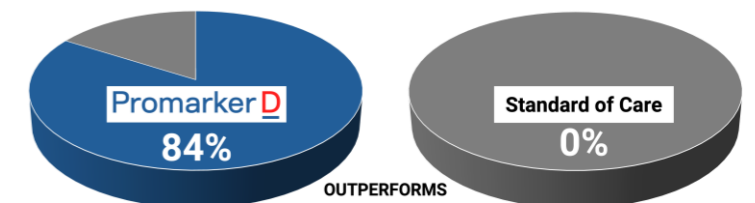
Conclusion: PromarkerD can identify 'at-risk' patients who are asymptomatic for DKD, with canagliflozin offering a potential treatment that can improve their renal risk profile



Outperforms Standard of Care

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

Community based study of type 2 diabetes patients (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 [ASN (Nov 2021)]

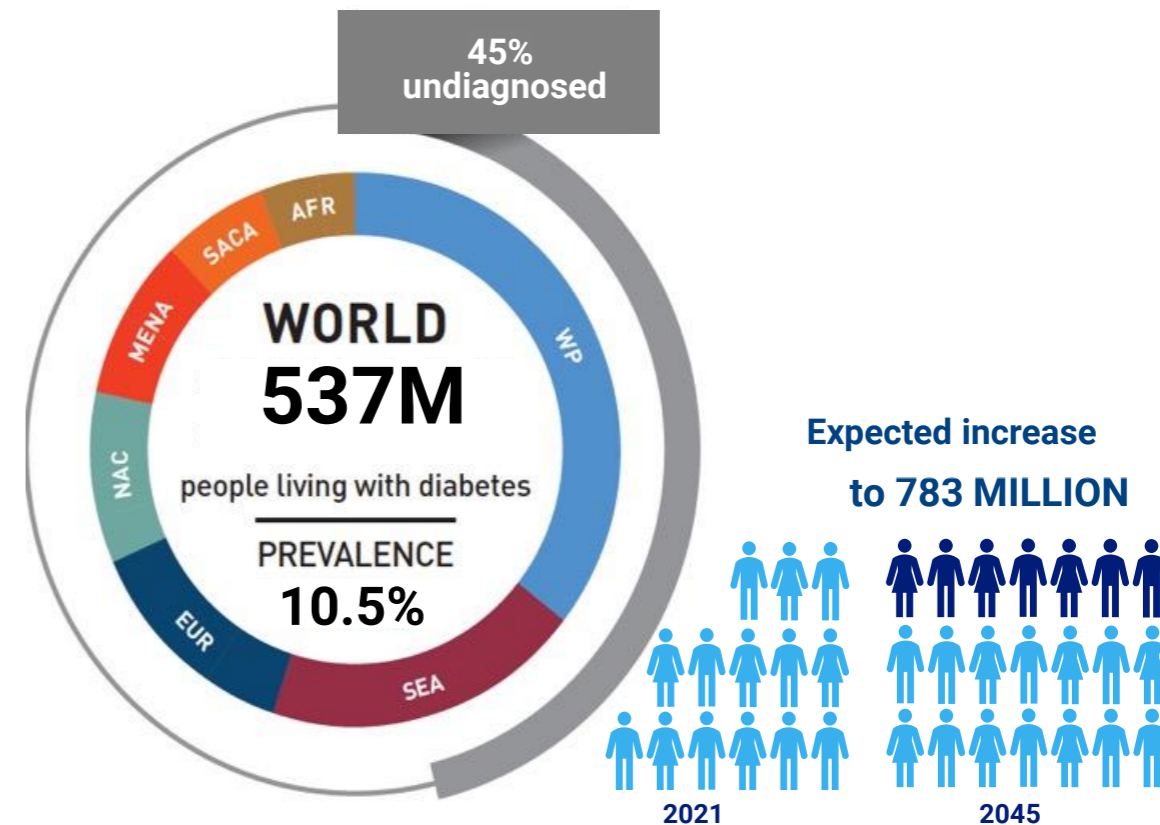


PromarkerD Market Opportunity

Diabetes incidence and Patent portfolio

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	Pending	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
			~340 million Total

1. International Diabetes Federation (IDF) Atlas 10th Edition 2021 [Age group 20-79 years]
2. Australia, Europe, 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 387m diabetics¹
- **Test is performed once per year per patient on average**
- **Test price of US\$150** [based on stakeholder engagement responses in a market access study]
- **Standard industry royalty rates range from 5-15%**