

Proteomics International

LABORATORIES LTD

ASX release

2 February 2023

ASX code: PIQ

Investor Presentation

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) is pleased to release a copy of the presentation to be provided by Dr Richard Lipscombe to delegates at Euroz Hartleys Healthcare Forum being held on 2 February 2023.

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

ENDS

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The background of the slide is a blurred photograph of a laboratory. In the foreground, a white pipette tip is positioned over a multi-well plate, which contains small yellow liquid droplets in several wells. The background is out of focus, showing more of the lab environment. Overlaid on the left side of the image are two blue circles: a large dark blue one and a smaller light blue one above it.

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LABORATORIES LTD

Investor Presentation

Euroz Hartleys Healthcare Forum

2 February 2023

Dr. Richard Lipscombe

Managing Director

Disclaimer

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Proteomics International Laboratories Ltd



ASX: PIQ

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

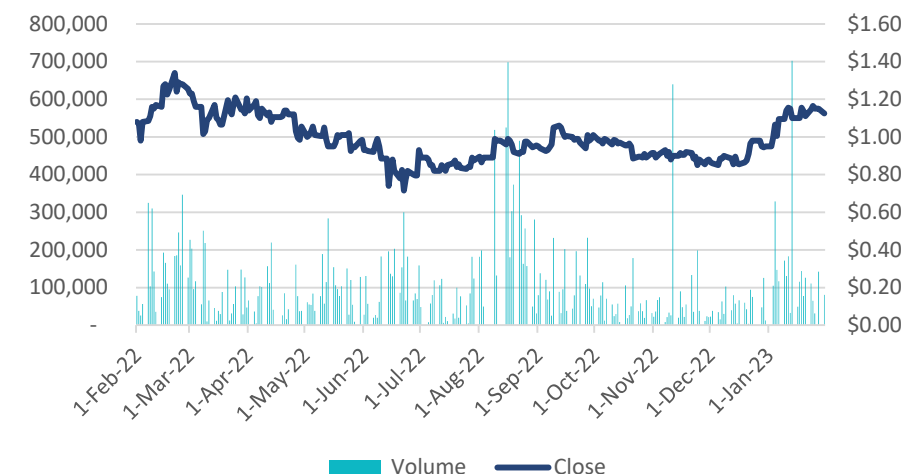
- ASX listed; 29 staff; headquartered on QEII Medical Campus, Perth, WA
- Raised \$8m (gross) in heavily oversubscribed placement (Aug 22)
- Manufacturing (\$0.4m; May 22) and Dx facility (\$0.85m; Oct 22) funding
- Implementing expansion strategies to accelerate growth

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%

Volume

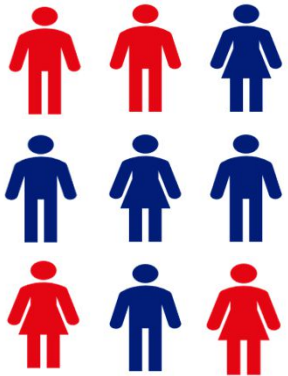
Price (\$)



Promarker – Platform Technology



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

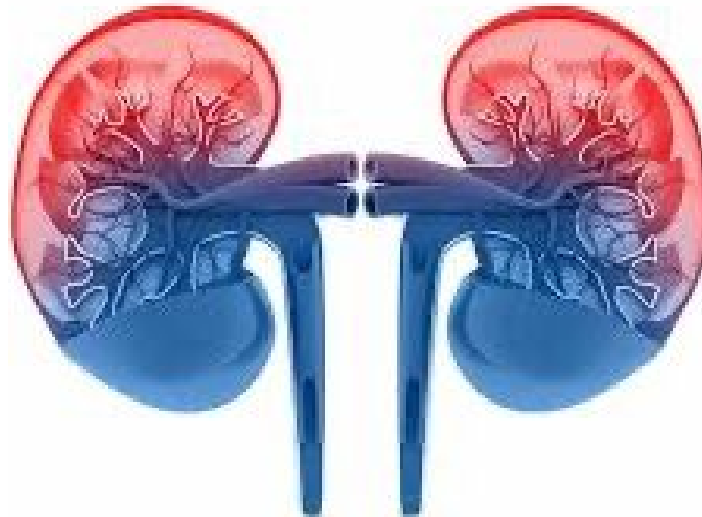


The platform identifies and links the unique protein biomarkers to specific diseases, enabling Proteomics International to create novel diagnostic tests

Promarker D

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 = **US\$130 Bn** per year in USA alone



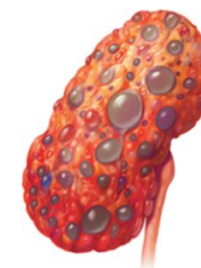
Roadblock



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



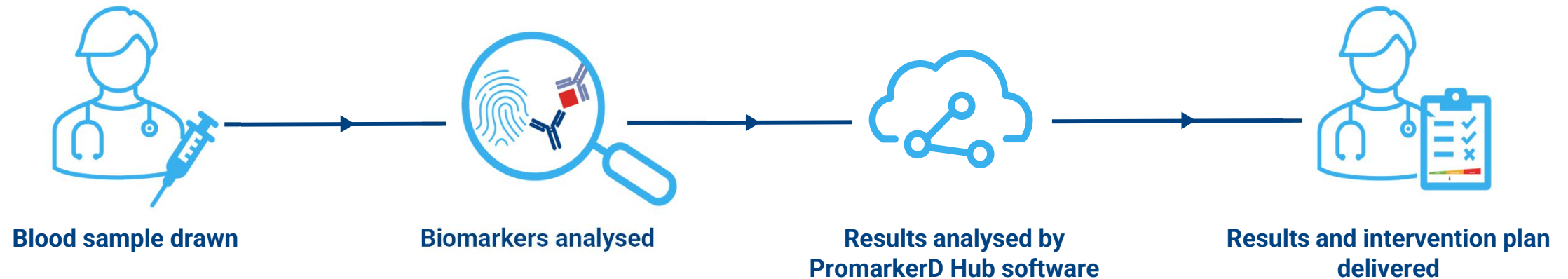
Healthy Kidney

PromarkerD is Revenue Ready

Key highlights towards a global roll-out

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 - 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

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:

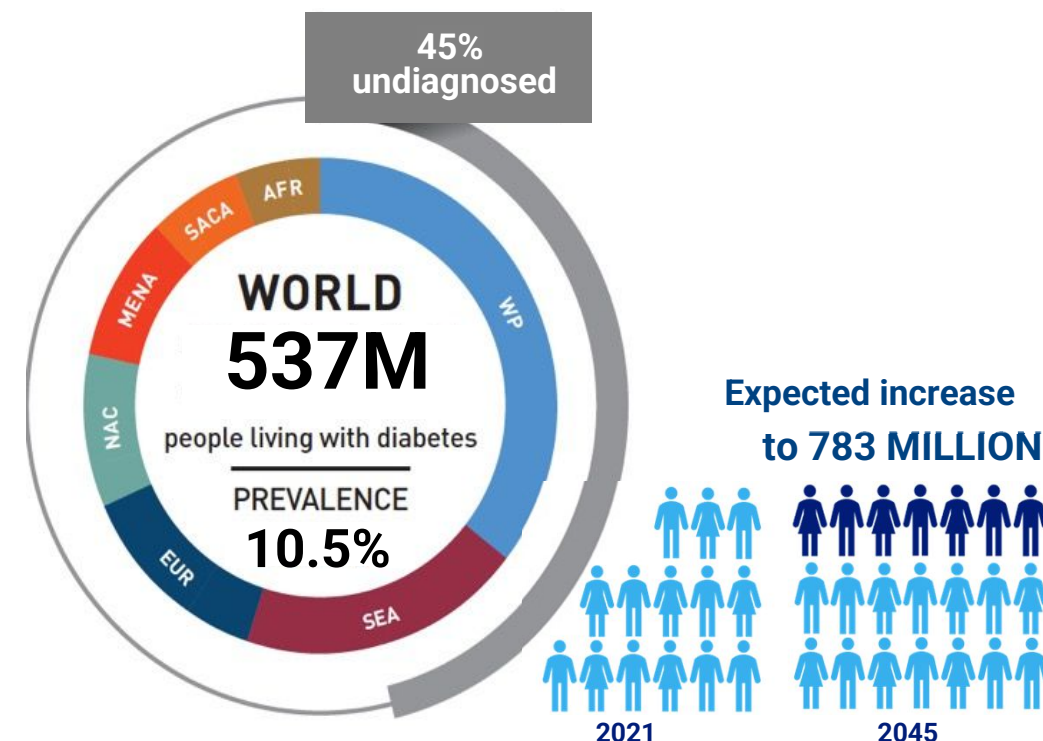
- change of lifestyle; and/or
- therapeutic drugs

PromarkerD 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	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
			~340 million Total

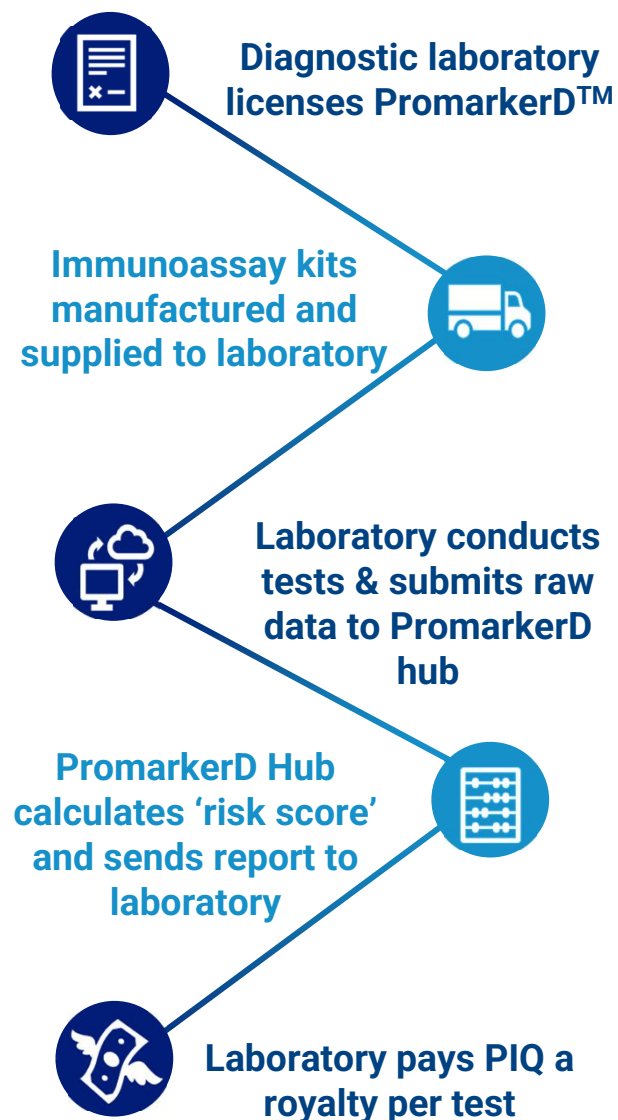
1. International Diabetes Federation (IDF) Atlas 10th Edition 2021 [Age group 20-79 years]
2. Australia, Europe, HK, USA patent family also covers use of the test for **any form of kidney disease** (NB further studies are required to prove efficacy of PromarkerD for applications beyond DKD)
3. Covers 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 diabetics¹
- 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



PromarkerD Diabetic Kidney Disease Risk Assessment

Early detection can significantly help prevent serious kidney damage.

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*



Israel

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

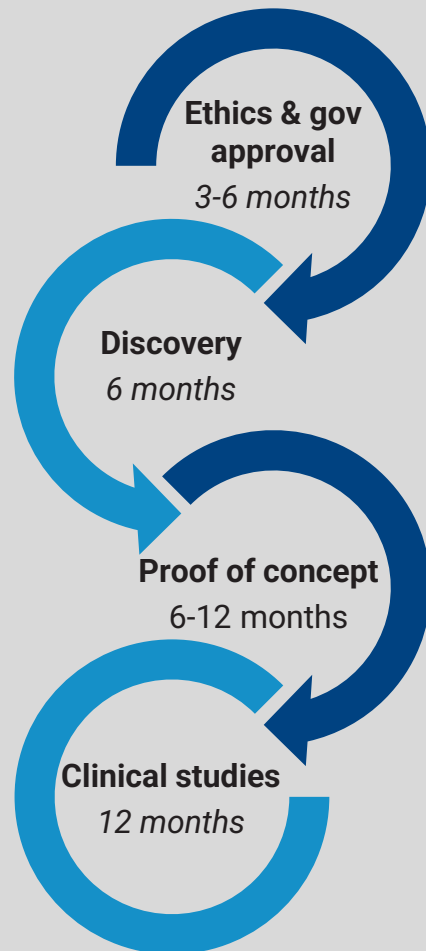
ZOTAL

Diagnostics Pipeline



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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

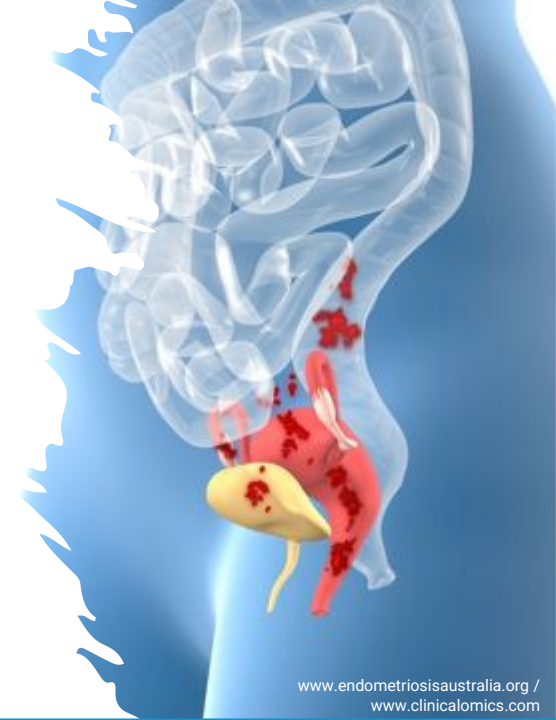
Biomarker Research Pipeline	PRE-START	RESEARCH	DEVELOPMENT		COMMERCIALISATION
	Ethics & Governance	Discovery	Proof of Concept	Clinical Study/ Validation	
Diabetic Kidney Disease					Promarker <u>D</u>
Endometriosis					
Giardia					
Asthma & COPD					
Plant Dieback					
Diabetic Retinopathy					
Oxidative Stress (2-tag)					OxiDx Pty Ltd
Oesophageal Cancer					
Retinopathy (ARC Centre)					

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**



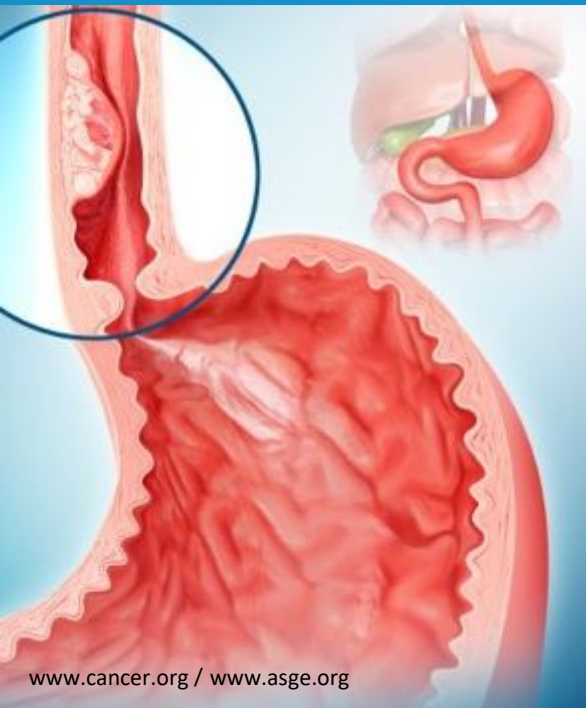
www.endometriosisaustralia.org/
www.clinicalomics.com

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**

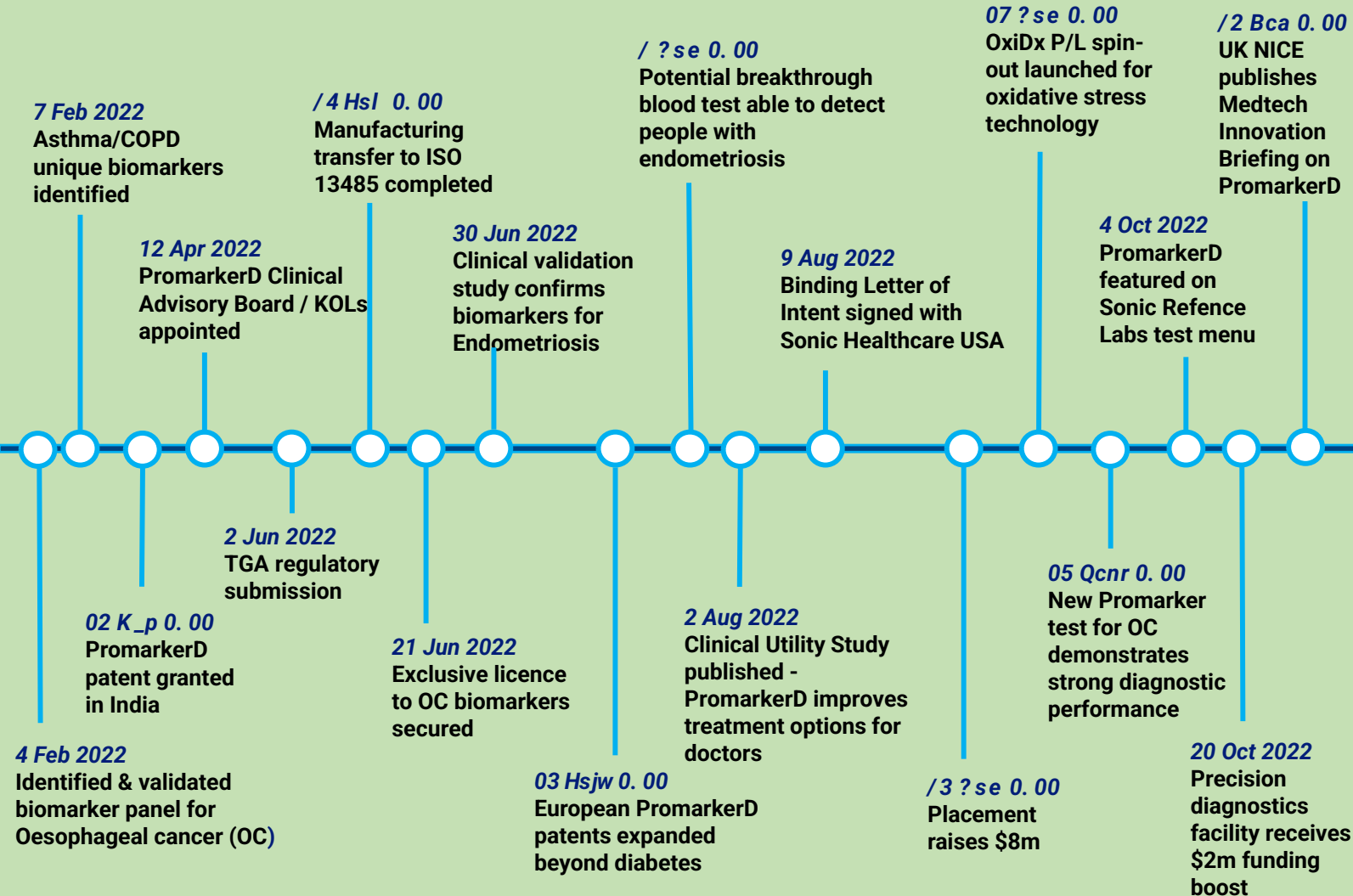


Timeline & Milestones

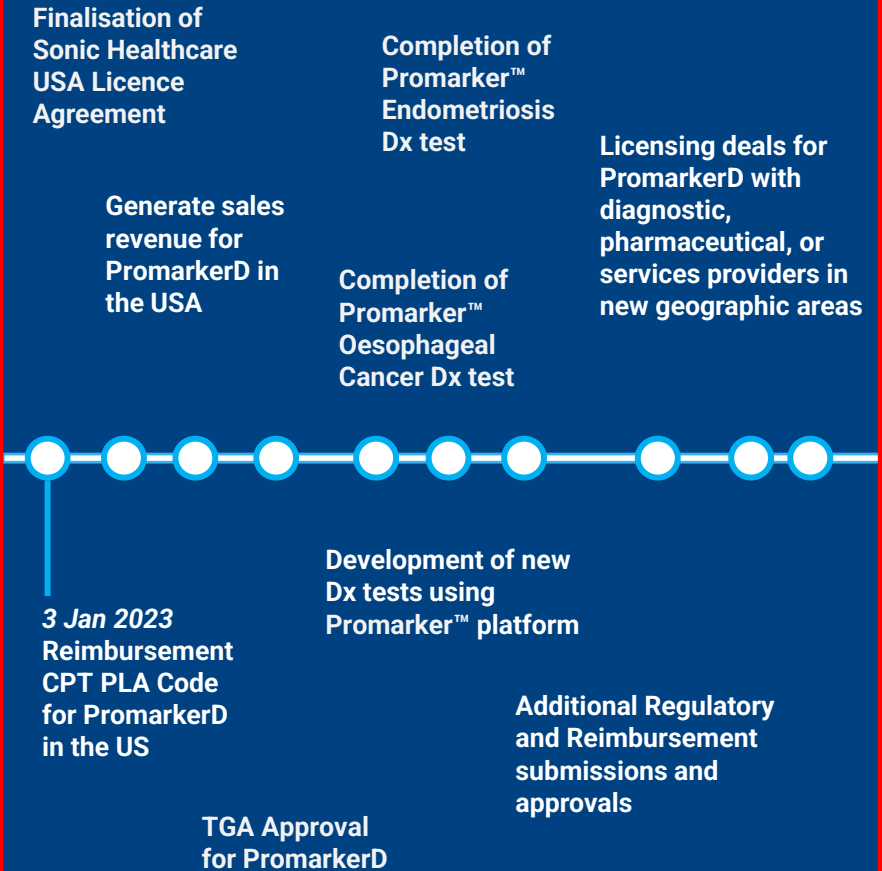


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2022 Achievements



2023 Targets & Milestones



Value Inflection Points



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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	Company Focus	Market Capitalisation	Share Price	FY22 Revenue	FY22 Net Profit/Loss
	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
	Innoviq Ltd	IIQ.ASX	Early stage in-licensed IP for various cancer diagnostics.	A\$60m	A\$0.65	A\$0.3m	A\$18m loss
	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)	~A\$57m loss (9 months to 30 Sep 22)
	Renalytix AI	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	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 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)

Source: Company filings. Market data as at 30 Jan 2023, exchange rates of GBP:AUD 1.74 and USD:AUD 1.41

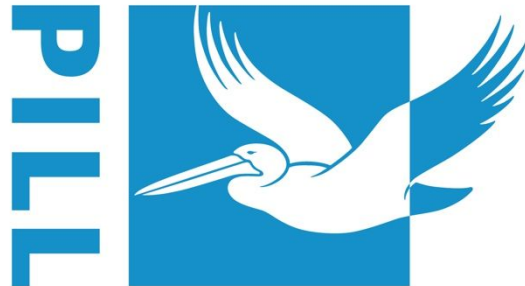
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Supplemental



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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.

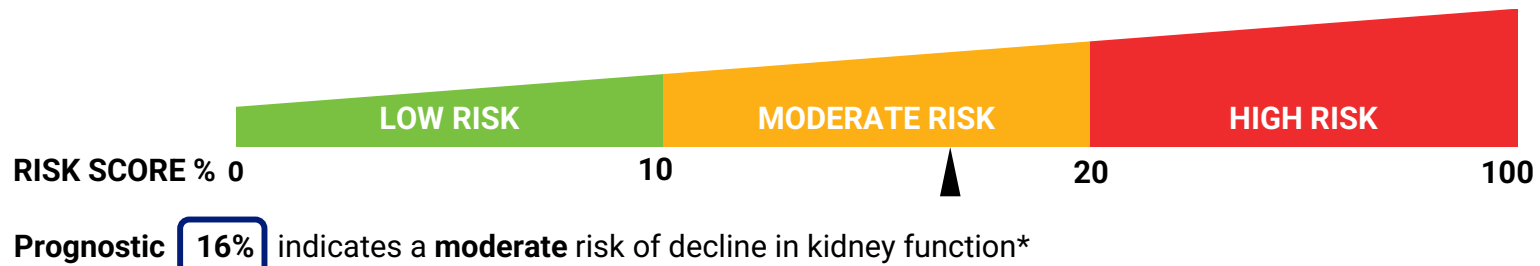


Dr Robyn Elliott PhD Inorganic Chemistry (Monash), BSc(Hons) Chemistry (Monash), Non-Executive Director

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



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 monitoringOptimisation of lifestyleReview of glycemic targets and managementReview non-glycemic risk factorsAvoidance of potentially nephrotoxic drugs	Test every 6 months
High Risk	<ul style="list-style-type: none">Very close monitoringIntensive management strategies based on those for 'Moderate risk' aboveUtilisation 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 patients with T2D 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 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 [ASN (Nov 2021)]

