



Proteomics International

LABORATORIES LTD

ASX Release

24 November 2022

ASX code: PIQ

AGM Chairman's Address and Investor Presentation

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) is pleased to release a copy of the Chairman's Address to be provided by Mr Neville Gardiner and the Investor Presentation to be provided by Dr Richard Lipscombe to shareholders at the Annual General Meeting to be held in Perth commencing at 9:30 am AWST today.

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

ENDS

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

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

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Chairman's Address

My name is Neville Gardiner, and as Chair of the company it is my pleasure to welcome you to the 8th Annual General Meeting of shareholders of Proteomics International Laboratories.

It is now after 9:30 am, and as we have a quorum of shareholders present, I declare the meeting open.

The notice convening today's meeting was made available to shareholders on the 19th of October 2022 and lodged with ASX on that date. Consequently, I will take the notice as read.

Firstly, let me introduce the members of your Board:

Dr Richard Lipscombe, Managing Director, Mr Paul House, Dr Robyn Elliott and Mr Roger Moore.

Also present here today are Ms Karen Logan, Company Secretary and Ms Ashleigh Woodley, representing BDO, our independent auditor.

I would also like to acknowledge our former Chair, Mr Terry Street who is with us in the audience today.

Financial Year 2022 was a very busy period for the company with many highlights that are set out in our Annual Report. We have also had very busy start to FY23 including:

- Exciting progress on our potential test for endometriosis;
- Significant advances in the commercialisation of the PromarkerD test including a binding Letter of Intent with Sonic Healthcare USA; and
- A highly successful \$8 million placement.

Richard will speak in more detail to the company's achievements in his presentation later this morning.

On behalf of the Board, I would like to thank Richard and the entire Proteomics team for their continuing professionalism and dedication. Their hard work has the potential to fundamentally improve millions of lives. I would also like to thank all long-standing shareholders for their continuing support and am pleased to welcome the more recent shareholders to the company. We have a very promising future.

I will now turn to the formalities of the meeting.



ASX: PIQ

Proteomics International

LABORATORIES LTD

AGM Presentation

2022 – an inflection point

24 November 2022

Dr. Richard Lipscombe
Managing Director

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

- Raised \$8m (gross) in heavily oversubscribed placement (Aug 22)
- R&D Tax Rebate of \$1.7m received (Oct 22)
- Manufacturing (\$0.4m; May 22) and Dx facility (\$0.85m; Oct 22) funding
- Implementing expansion strategies to accelerate growth

Corporate Snapshot – 21/11/2022

ASX code	PIQ
Share Price	A\$0.91
Shares on issue (+7.6m options)	115m
Market Capitalisation	A\$105m
Revenue & other income – FY22	A\$3.4m
Cash (30 Sept '22) + \$1.7m R&D rebate rec'd Q4 CY22	\$6.4m
Net cash burn – FY22	A\$3.5m
Directors Shareholding	18.1%



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. Neville 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, Mr Moore was appointed Novo Nordisk's Senior Vice President, Japan & Oceania Region. Roger 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.



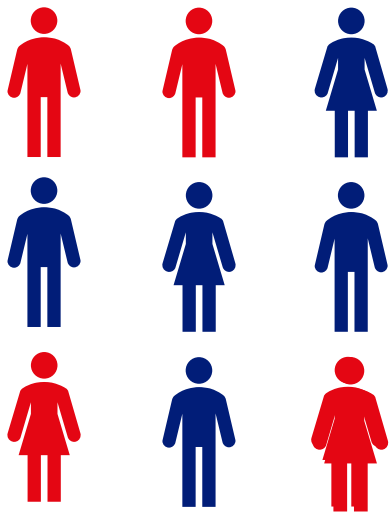
Dr Robyn Elliott PhD (Monash), BSc(Hons) (Monash), Non-Executive Director

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. Robyn is also a non-executive director of PolyNovo Limited (ASX:PNV).

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

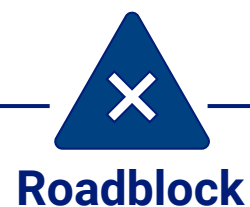


Problem & Solution



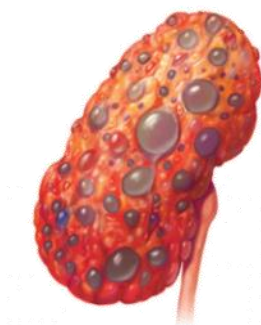
The Problem

- **537 million 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



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



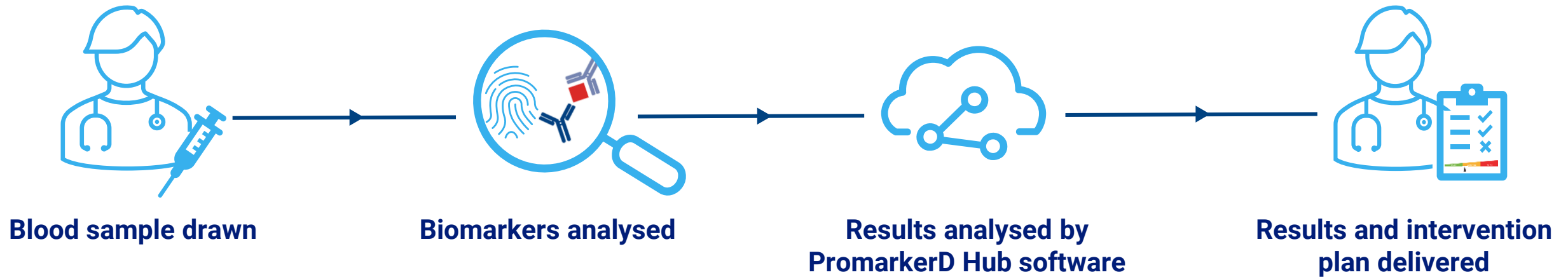
Healthy Kidney

PromarkerD is Revenue Ready

The PromarkerD predictive test is rolling out in key markets

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		Identified pathway to obtain a unique PLA reimbursement code & payment coverage in the USA; 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

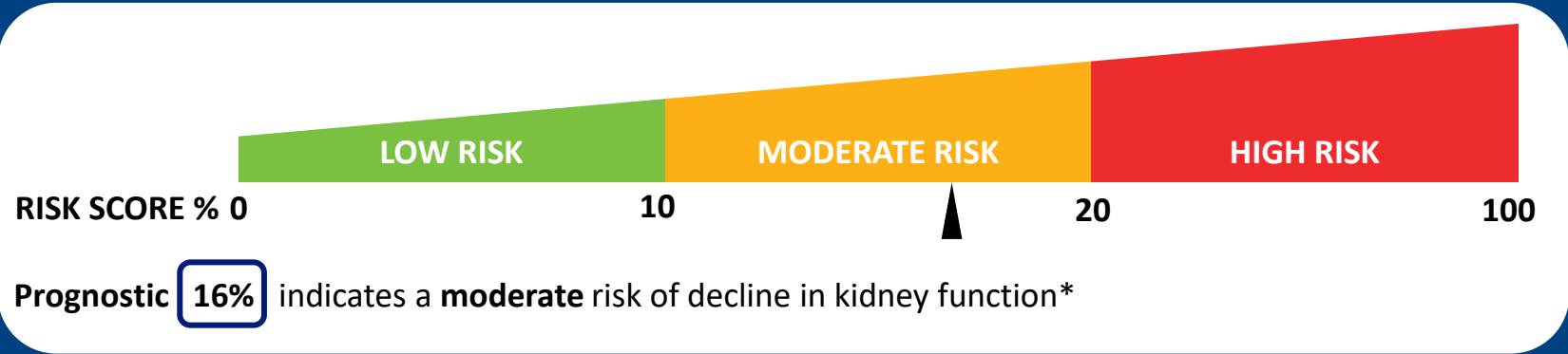
Clinician delivers results to patient

Depending on results, intervention may include:

- change of lifestyle; and/or
- therapeutic drugs

PromarkerD – Results & Intervention

How PromarkerD™ results are delivered



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/1.73m²) 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 $p = 0.002$)

Conclusion: PromarkerD can identify 'at-risk' patients who are asymptomatic for DKD, and canagliflozin offers a potential treatment that can improve the patient's renal risk profile [ADC (2021); manuscript in preparation]

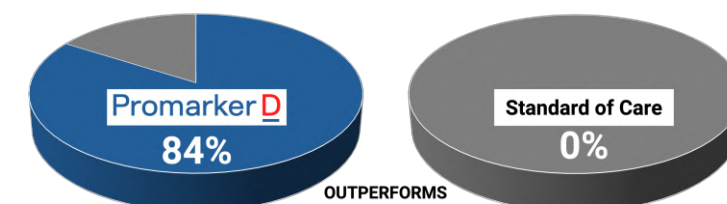


Outperforms Standard of Care

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

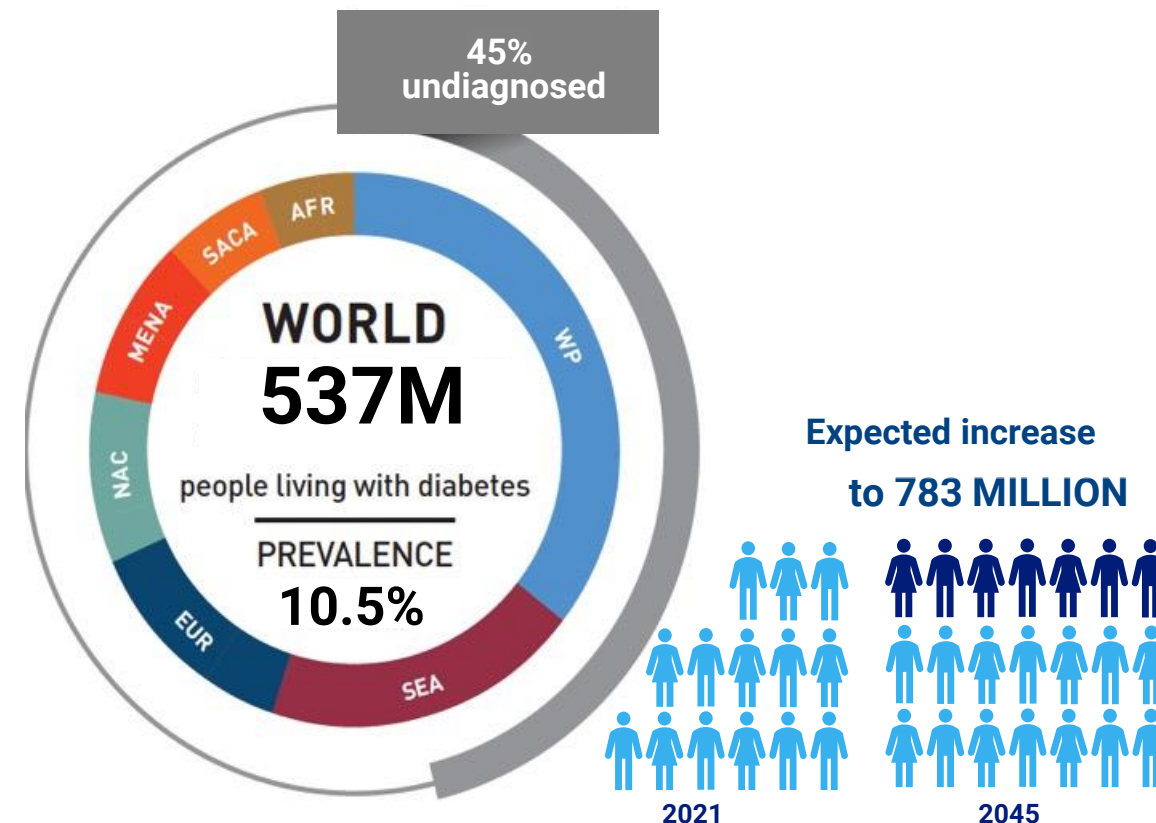
Country	Patent/Application No	Patent Status	No. Diabetics ¹
Australia	2011305050	Granted	1,491,800
Brazil	BR112013006740	Granted	15,733,600
Canada	2811654	Granted	2,974,000
China	ZL201180053583.9	Granted	140,869,600
Europe ^{2,3}	3151012	Granted	61,425,100
Hong Kong	18115912.3	Granted	686,000
India	3012/DELNP/2013	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

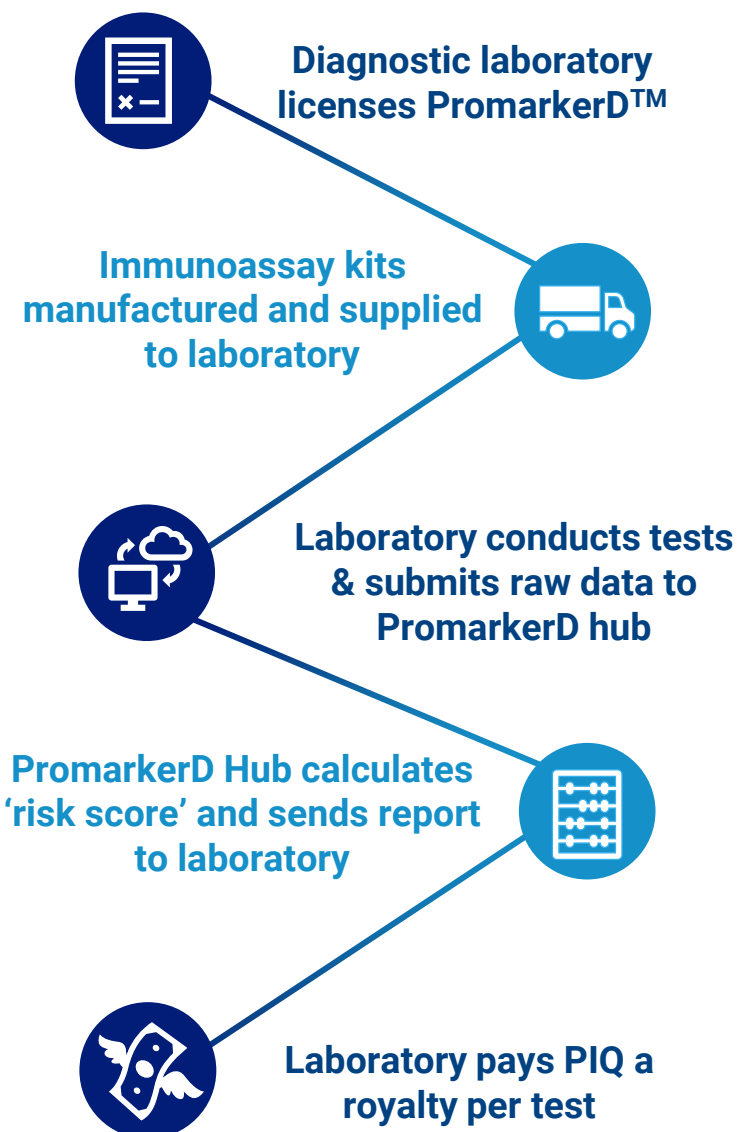
4. USA patent further extended to cover **method for identifying drugs for abnormal kidney function** using one of the PromarkerD biomarkers (CD5L)



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 available** on Sonic Reference Laboratory (USA) website
- Outcome of **PLA reimbursement code** registration expected Q1 CY23

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) assessment ongoing



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

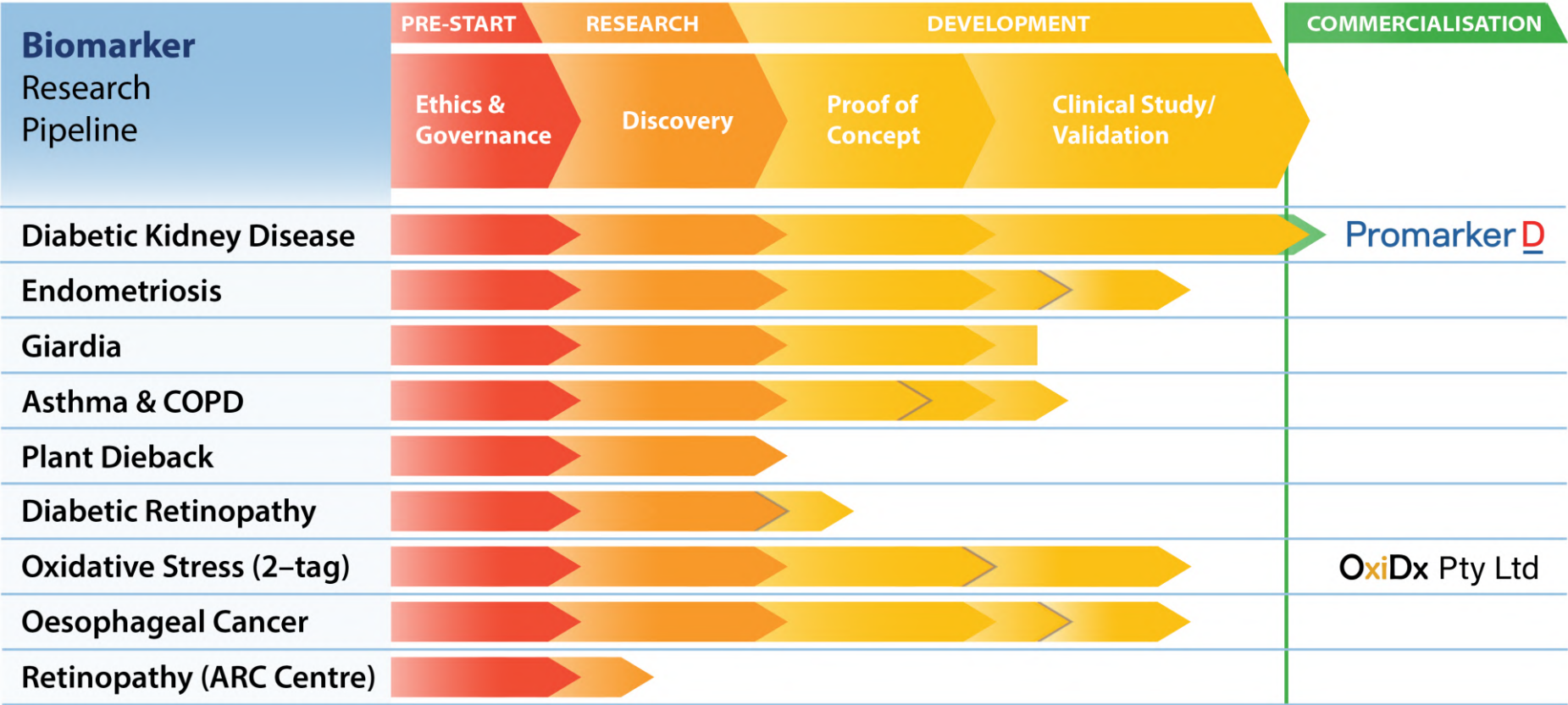
The Promarker™ Research Pipeline & Timeline



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

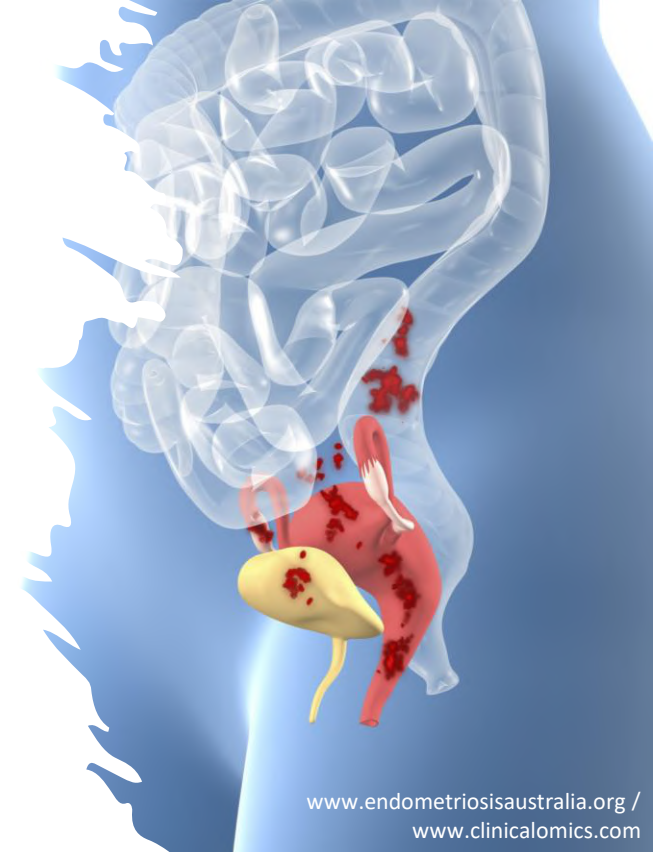


In Development: Endometriosis

- 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**



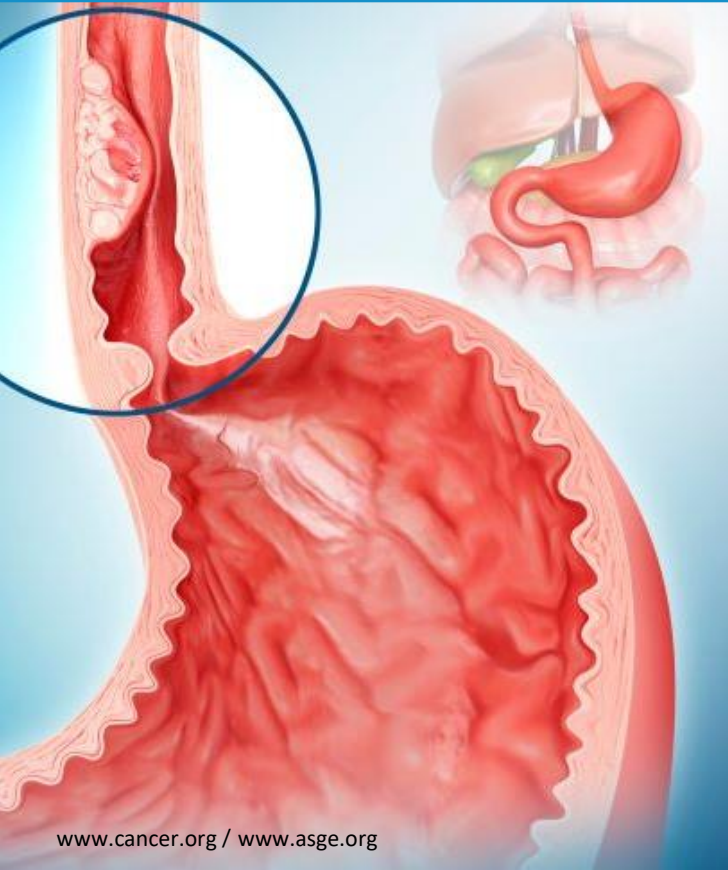
www.endometriosisaustralia.org /
www.clinicalomics.com

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**

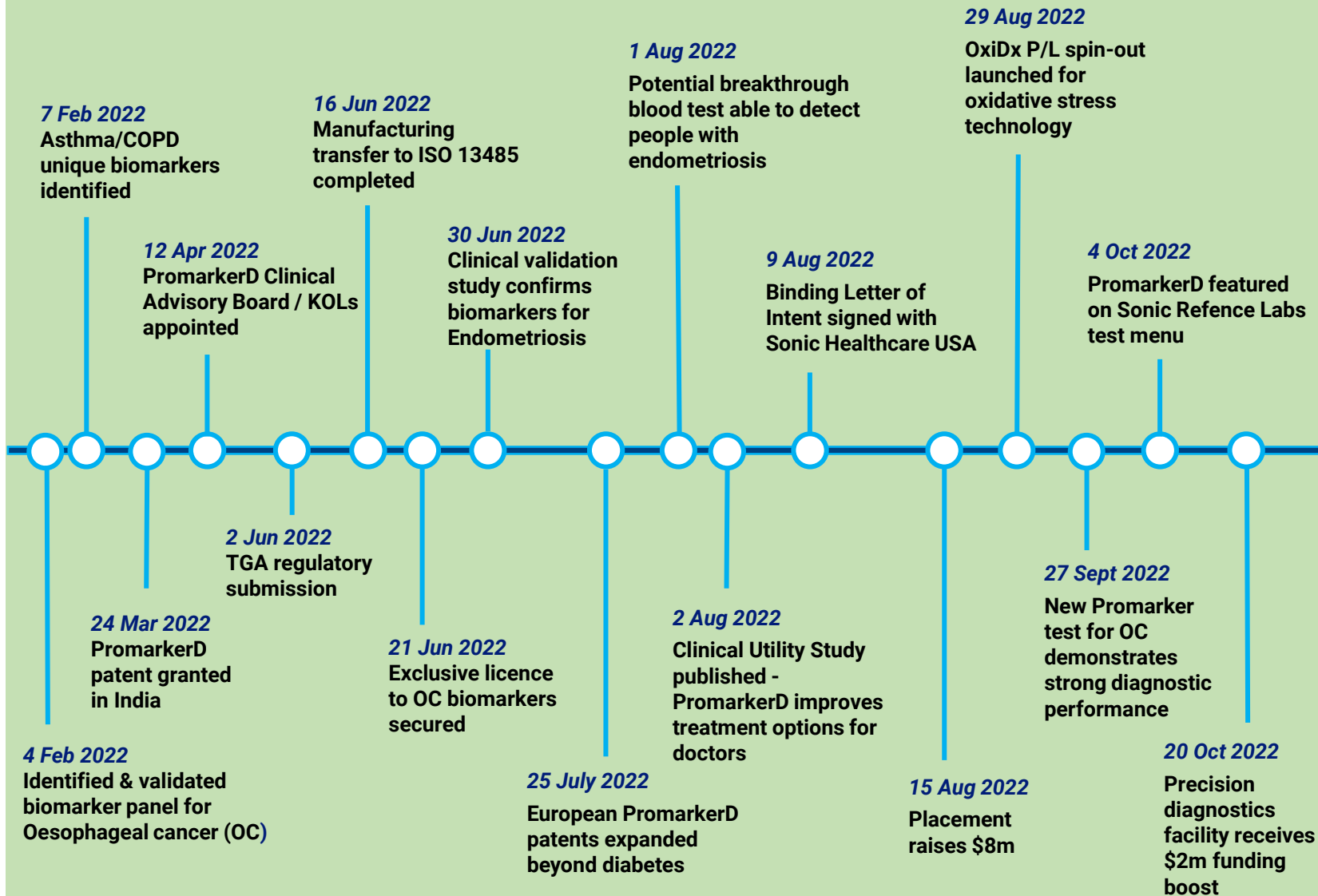
Promarker™ for Oesophageal Cancer and Barrett's esophagus

- 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**

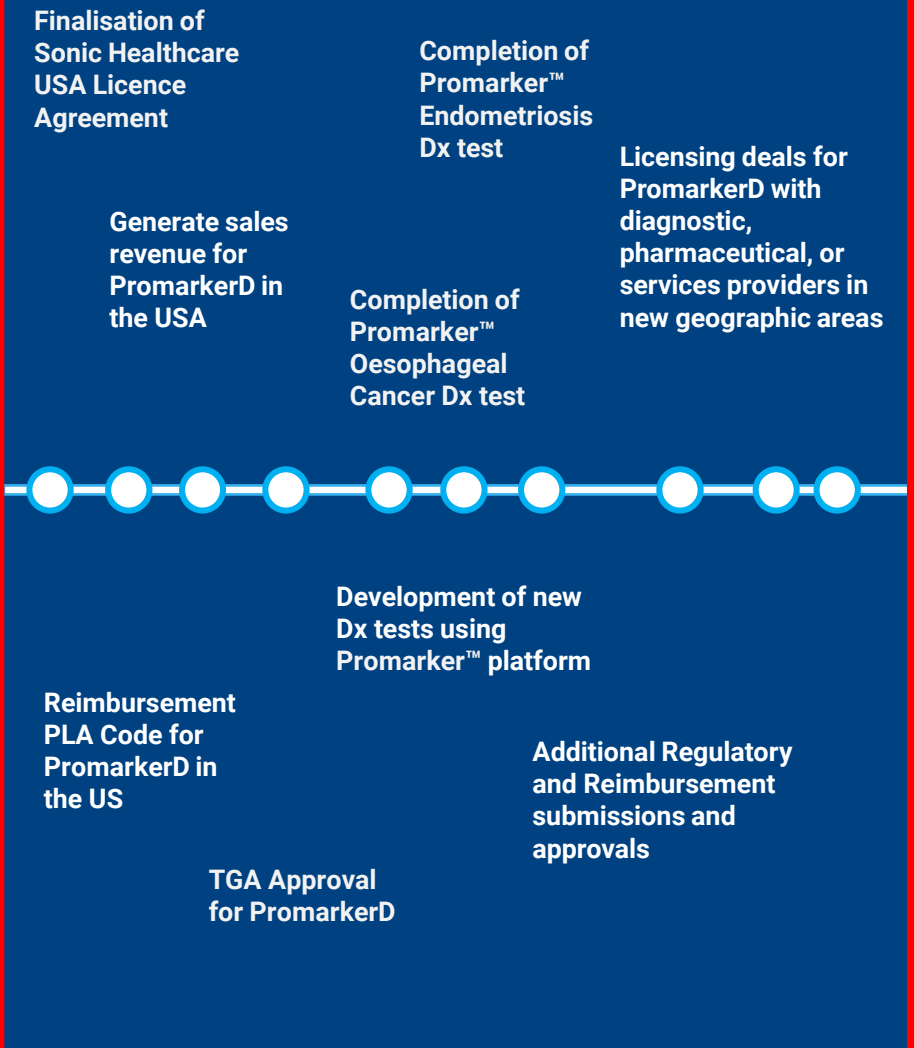


Timeline & Milestones

2022 Achievements



2023 Targets & 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 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 in Key Markets			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

Peer Comparison

		Stock Code	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\$105m	A\$0.91	A\$1.7m	A\$4.9m loss
	Innoviq Ltd	IIQ.ASX	Early stage in-licensed IP for various cancer diagnostics.	A\$51m	A\$0.555	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\$109m	US\$1.98	~A\$0.3m (6 months to 30 Jun 22)	~A40m loss (6 months to 30 Jun 22)
RENALYTIX AI	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\$87m	65p	~A\$2.1m (6 months to 31 Dec 2021)	~A\$43m loss (6 months to 31 Dec 2021)
	Rhythm Biosciences	RHY.ASX	Pre-commercialisation proteomics derived diagnostic test for colon cancer licensed from CSIRO.	A\$243m	A\$1.12	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\$2.31Bn	A\$7.36	A\$24m (6 months to 30 Jun 2022)	A\$71m loss (6 months to 30 Jun 2022)

Source: Company filings. Market data as at 22 November 2022, exchange rates of GBP:AUD 1.79 and USD:AUD 1.51

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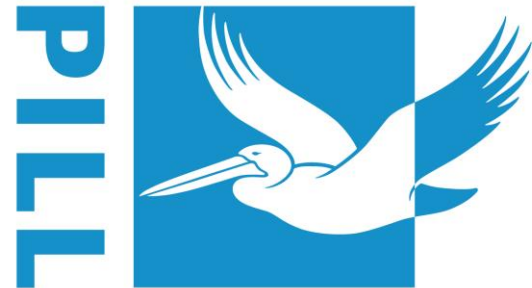
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