

Proteomics International

LABORATORIES LTD

ASX Release
25 November 2021

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 Terry Sweet 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) 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

Good Morning Ladies and Gentlemen

My name is Terry Sweet, and as Chair of the company it is my pleasure to welcome you to the 7th 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 26th of October 2021 and lodged with ASX on that date. Consequently, I will take the notice as read.

Firstly, let me introduce the members of your Board:

Present in person are Dr Richard Lipscombe, Managing Director, Mr Paul House, Mr Neville Gardiner, and Ms Karen Logan, Company Secretary. Present by video link are Dr Robyn Elliott in Melbourne and Mr Roger Moore in Sydney. Also present here today is Mr Neil Smith, representing BDO, our independent auditor.

I would particularly like to welcome Dr Elliott and Mr Gardiner, who have recently joined the board of PIQ, and who between them bring a wealth of experience in technical, corporate, financial and commercial areas.

As you will know, at the end of this AGM I will step down from the board of PIQ, and Mr Gardiner will take on the role of Chair of your company. Since listing on ASX in 2015 the company has made great progress, steadily building on the small private company founded by Dr Lipscombe twenty years ago last February.

The positive results of the initial clinical study of PromarkerD have been firmly and conclusively validated by subsequent published, peer-reviewed studies.

The clinical advantages of the use of the PromarkerD test in assessing risk of kidney disease over current standard of care is unequivocal.

The reduction of healthcare costs by predicting who is likely to suffer kidney disease, thereby allowing steps to be taken to avoid or delay the condition, are very significant.

Dr Lipscombe will speak in more detail to the above, however as I leave the company, these are milestone achievements for which I am proud to have played a small part.

Your company is now poised to deliver this diagnostic test, PromarkerD for use by doctors, for the benefit of their patients: this will not only reward those who have invested in the company, but will fulfil the company's vision "to help create a world where disease is detected early and cured simply".

I will now move to the formalities of the meeting.



ASX: PIQ

Proteomics International

LABORATORIES LTD

AGM Presentation

25 November 2021

Dr. Richard Lipscombe

Managing Director

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

PromarkerD

- Predictive test for early identification of diabetic kidney disease (DKD)
- Cost-effective, easy to use, patented technology
- Strong pipeline of novel tests in development – Endometriosis, Asthma & COPD, Oesophageal cancer, Gastro, 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 offsets the cash burn from R&D and product development

Financial & Corporate

- Raised \$6m in heavily oversubscribed placement (Oct 20)
- Senior management team expanded (Jun 21) + Board renewal (Nov 21)
- R&D tax incentive rebate of ~A\$1.2 million due December 21
- Implementing expansion strategies to accelerate growth

Corporate Snapshot – 19/11/2021

ASX code	PIQ
Share Price	A\$0.96
Shares on issue (+8.4m options)	105m
Market Capitalisation	A\$101m
Cash (30 Sept 2021)	A\$4.4m
Revenue & other income – FY21	A\$3.0m
Net cash burn – FY21	A\$2.9m
Directors Shareholding	22%



Board of Directors



Terry Sweet FAICD, Chairman (Retiring at 2021 AGM)

Director of several listed companies over the past 30 years in both executive and non-executive capacities. Companies include XRF Scientific Ltd, where he was MD for 4 years, Western Biotechnology Ltd, Heartlink Ltd, & Scientific Services Ltd.



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).



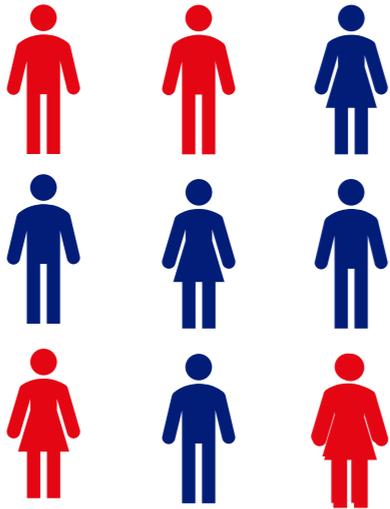
Neville Gardiner BBus (Accounting and Business Law) (Curtin), CA, MAICD, Non-Executive Director / Chair-elect

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 Deloitte in 2016, where he became Partner in their M&A Advisory team.

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

- **463 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

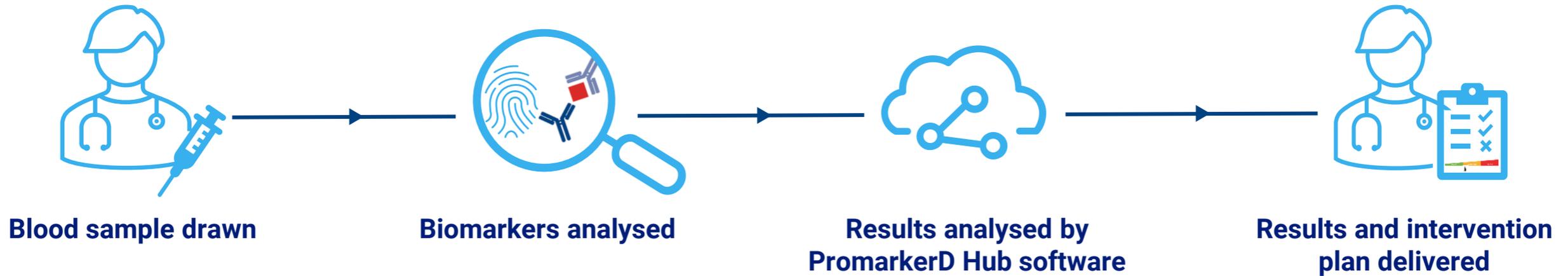
PromarkerD is Revenue Ready



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

Enormous Market	✓	463m 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) – access to 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	●	Specialist companies working to enable reagent supply and ISO 13485 certified kit manufacture
Reimbursement	●	Identified pathway to obtain a unique reimbursement code & payment coverage in the USA: Economic Health Benefit & Clinical Utility demonstrated
Regulatory Approvals - ongoing	●	Engaging with partners and national regulators [US sales to utilise the LDT pathway with CLIA laboratories, prior to FDA approval]
Generate Sales Revenue	●	First distribution agreements for PromarkerD immunoassay signed – initial sales pending

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

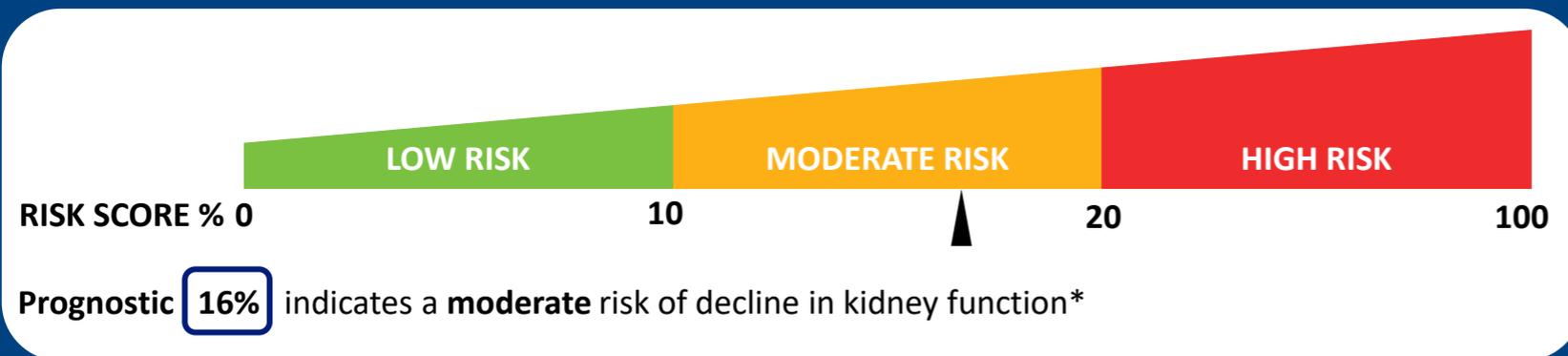
Clinician delivers results to patient

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 every
12-24 months

Moderate Risk

- More frequent monitoring
- Optimisation of lifestyle
- Review of glycemic targets and management
- Review non-glycemic risk factors
- Avoidance of potentially nephrotoxic drugs
- Utilisation of therapeutic drugs

Test every
6 months

High Risk

- Very close monitoring
- Intensive management strategies based on those for 'Moderate risk' above with optimisation of treatments for diabetes and other risk factors

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)]

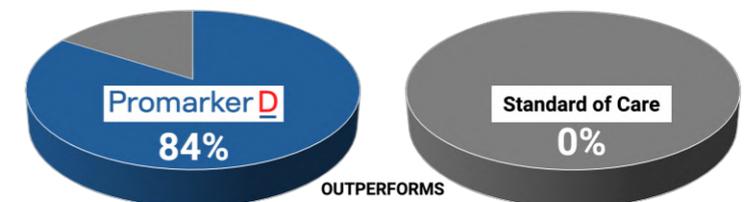
Conclusion: PromarkerD can identify 'at-risk' patients who are asymptomatic for DKD, with canagliflozin offering a potential treatment that can improve their renal risk profile



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)]

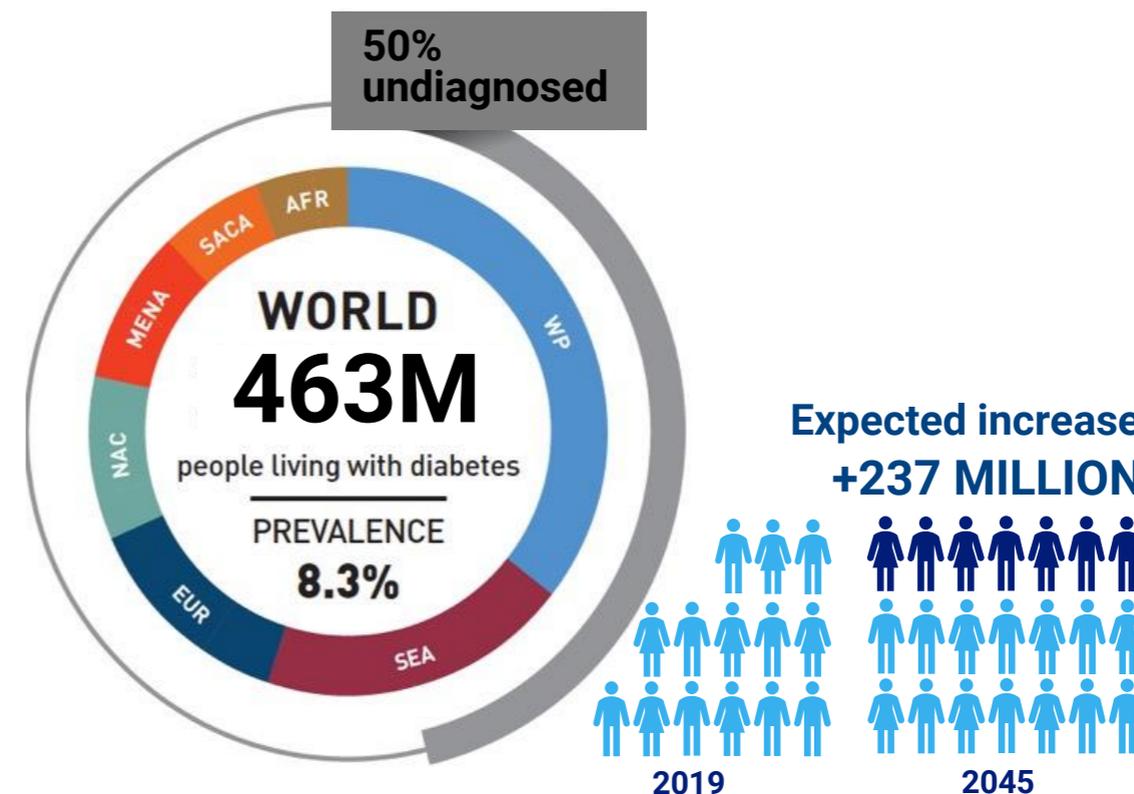


PromarkerD Market Opportunity

Diabetes incidence and Patent portfolio

Country	Patent/Application No	Patent Status	No. Diabetics ¹
Australia	2011305050	Granted	1,288,300
Brazil	BR112013006740	Granted	16,780,800
Canada	2811654	Granted	2,793,500
China	ZL201180053583.9	Granted	116,446,900
Europe ^{2,3}	3151012	Granted	59,322,100
Hong Kong	18115912.3	Pending	723,400
India	3012/DELNP/2013	Pending	77,005,600
Indonesia	W00 2013 01585	Granted	10,681,400
Japan	2013-528474	Granted	7,390,500
Russia	2596486	Granted	8,288,500
Singapore	188527	Granted	640,400
USA ^{2,4}	US 9,146,243	Granted	30,987,900
			332,349,300 Total

1. International Diabetes Federation (IDF) Atlas 9th Edition 2019 [Age group 20-79 years; Total = Diagnosed (48.7%) + Undiagnosed 51.3%]
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 29.6m 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 covers 332m 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%**

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%)
- Product registration expected Q1 CY22

Italy

- Licence with Medical Horizons SRL for immunoassay test
- 3.7m type 2 diabetics (8%)
- Test registered for use with Italian Ministry of Health
- Sales expected Q4 CY21 (delayed by COVID-19)

Israel

- Licence with Zotal Ltd for immunoassay test
- 0.6m type 2 diabetics (12%)
- Product registration on-hold pending ISO 13485 manufacturing

Targeted Licensing Transactions

United States

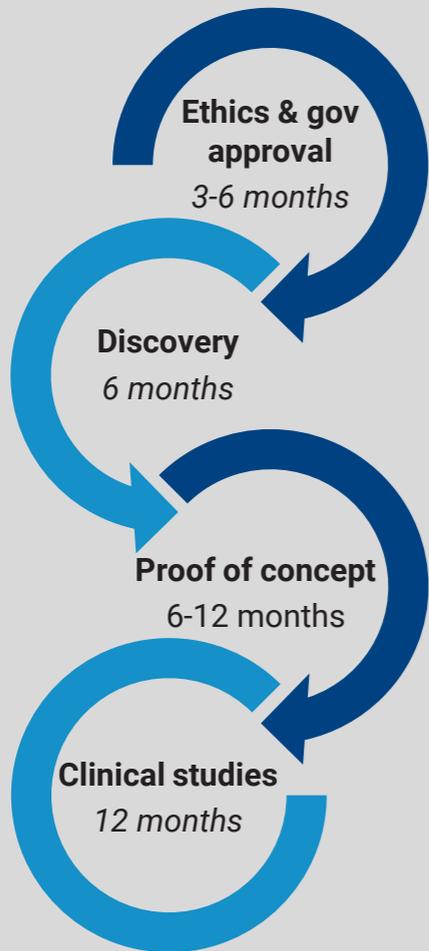
- Discussions ongoing with multiple national/global US diagnostic companies

RoW

- Actively targeting potential partners in key global jurisdictions

Diagnostics Pipeline

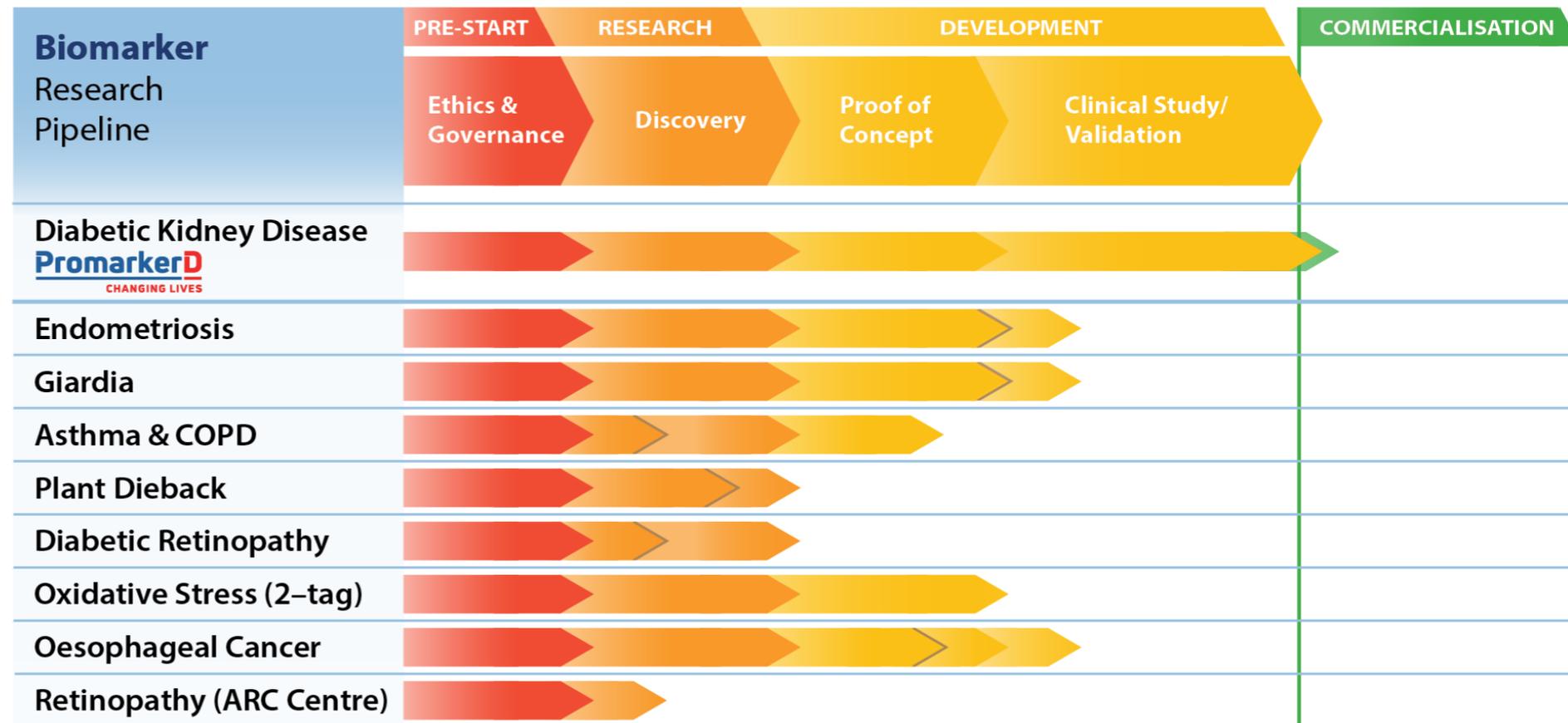
The Promarker™ Research Pipeline & Timeline



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



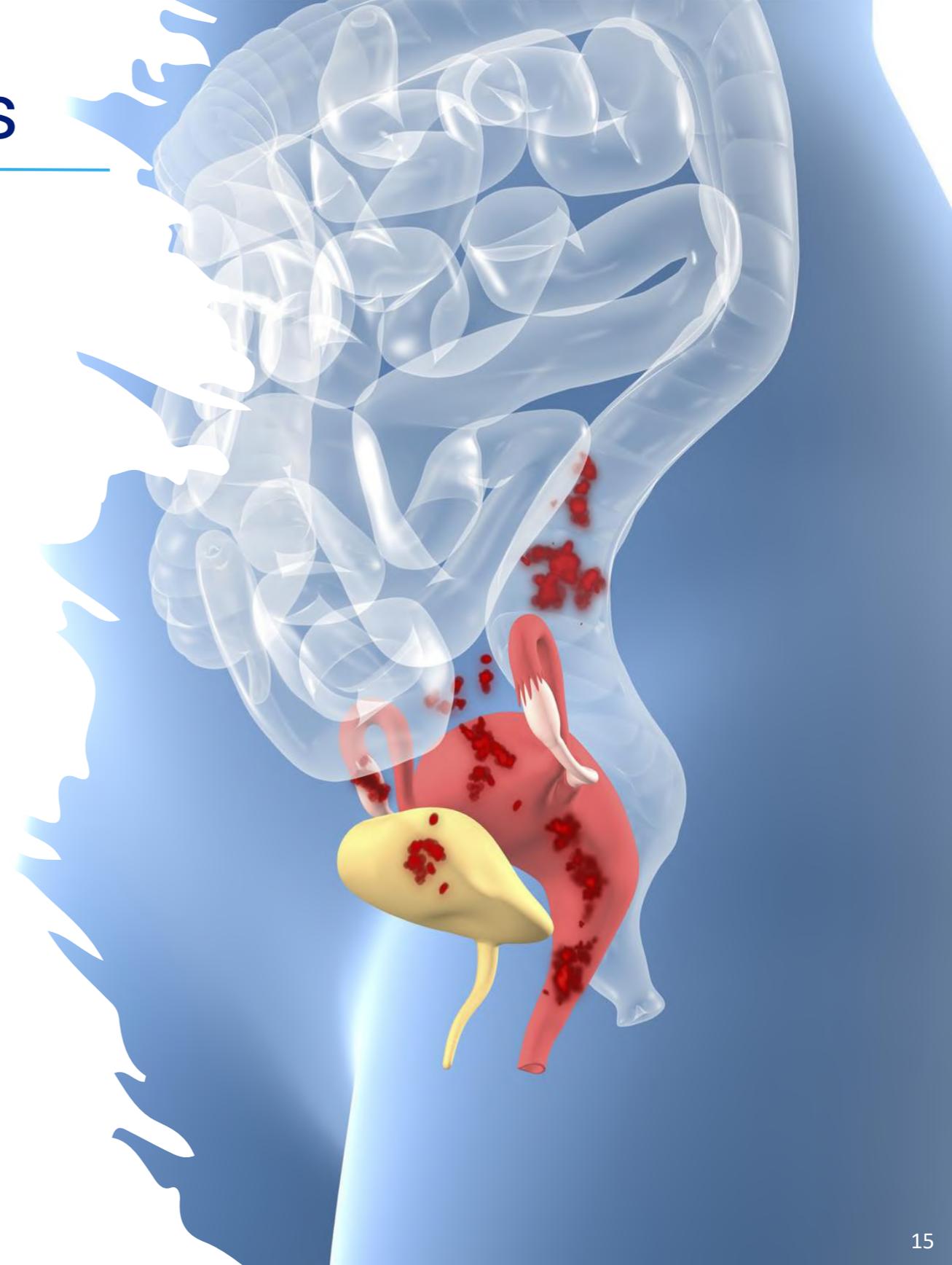
In Development: Endometriosis

What is Endometriosis?

- A debilitating condition in which tissue that normally lines the uterus grows outside the uterus (on the ovaries, fallopian tubes or the intestines)
- The most common symptoms are chronic pain and menstrual irregularities
- Diagnosis typically takes 7-12 years due to the lack of a diagnostic tool beyond invasive surgery = **Significant unmet medical need**
- **Affects 1 in 9 women and costs Australia \$9.7 billion a year – Global opportunity significantly higher**

Promarker™ for Endometriosis

- Novel biomarkers identified via the Promarker™ platform offer potential world-first blood test for endometriosis
- Proof of concept study performed on 54 women returned statistically significant results; Patent filed for new invention
- Collaboration with Royal Women's Hospital and University of Melbourne provides access to a large patient cohort (N=900) for a clinical validation study
- Results due Q1 CY22



Timeline & Milestones



ASX: PIQ

2021 Targets and Achievements

23 April 2021

Proteomics International receives ISO 13485 certification for medical device manufacture

13 May 2021

Study demonstrates major economic health benefit of PromarkerD

10 June 2021

Senior management team expanded: CCO & CFO appointed

16 July 2021

Successful results from Janssen Stage 2 study: *Canagliflozin* lowers PromarkerD risk scores

4 August 2021

Partnership with Royal Women's Hospital and Univ. Melbourne targets endometriosis clinical validation study

18 October 2021

Study shows PromarkerD significantly impacts clinical management decisions

16 Nov 2021

Board strengthened

23 Nov 2021

Distribution agreement for PromarkerD immunoassay – Britain

25 June 2021

Health Economics presented at American Diabetes Association

18 May 2021

Major analytical services contract for PK testing

29 April 2021

US FDA 513(g) application submitted

22 July 2021

Abcam (UK) engaged to produce specialist reagents for PromarkerD immunoassay

12 August 2021

Biotem (France) engaged for ISO 13485 manufacture of PromarkerD immunoassay Kit

5 Nov 2021

Results show PromarkerD significantly outperforms standard of care tests

24 Nov 2021

FDA advises De Novo pathway for PromarkerD

2021-22 targets

Major licensing deals for PromarkerD with diagnostic, pharmaceutical, or services providers

Reimbursement (Medicare) Code in the US

Manufacturing transfer to ISO 13485 completed

First Sales of PromarkerD immunoassay

FDA regulatory submission in the US

New results from the Promarker™ diagnostics pipeline – e.g. Endometriosis, Asthma/COPD, Oesoph. 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 2021-22

Milestone	Qtr	Dec'21	Mar'22	Jun'22	Sep'22	Dec'22	Impact
PromarkerD							
Licensing Deals		■	■	■	■	■	Drive global uptake and future revenue
First Sales in Europe		■					Drive revenue
ISO 13485 Manufacturing Site			■				Ability to supply global markets
US Reimbursement			■	■	■	■	CPT PLA code & Payor coverage
FDA Regulatory Submission			■				Build user confidence in product & assist second phase of test roll-out
Regulatory Approvals		■	■	■	■	■	Assist regional roll-out of test
Promarker™							
Endometriosis Study Results			■				New first-in-class diagnostic test
Diagnostics Pipeline Updates		■	■	■	■	■	New IP (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	FY21 Revenue	FY21 Net Profit/Loss
	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\$965m	735p	~A\$2.1m	~A\$43m loss
	AnteoTech ADO.ASX	Develops, commercialises, manufactures and distributes products for the life sciences research, diagnostics and medical device markets	A\$385m	A\$0.195	A\$0.9m	A\$6.2m loss
	Bard1 Life Sciences BD1.ASX	Early stage in-licensed IP for various cancer diagnostics.	A\$104m	A\$1.09	A\$0.5m	A\$12.3m loss
	Rhythm Biosciences RHY.ASX	Pre-commercialisation proteomics derived diagnostic test for colon cancer licensed from CSIRO.	A\$392m	A\$1.81	Nil	A\$6.6m 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\$101m	A\$0.96	A\$1.5m	A\$2.9m loss

Source: Company filings. Market data as at 22 November 2021, exchange rates of GBP:AUD 1.86 and USD:AUD 1.38

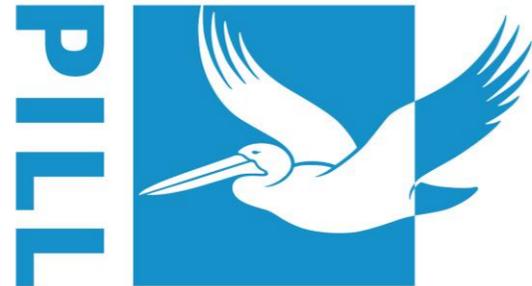
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