

Proteomics International

LABORATORIES LTD

ASX Release

20 July 2021

ASX code: PIQ

Investor Presentation

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) is pleased to release a copy of its latest investor presentation for a non-deal roadshow to existing and potential new institutional investors.

Authorised by the Board Proteomics International Laboratories Ltd (ASX.PIQ).

ENDS

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ASX: PIQ

Proteomics International

LABORATORIES LTD

Investor Presentation

July 2021

Non-deal Roadshow

Dr. Richard Lipscombe

Managing Director

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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)
- Patented, cost-effective, easy to use technology
- Additional tests in the pipeline – Endometriosis, Gastro, Oxidative Stress, Oesophageal cancer, Asthma & Lung Disease

Bioanalytical Services

- Strong demand from industry for these specialised analytics
- Year on year revenue growth
- Enhanced 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 (October 2020)
- Senior management team expanded (June 2021)
- Implementing expansion strategies to accelerate growth

Corporate Snapshot – 16/07/2021

ASX code	PIQ
Share Price	A\$1.08
Shares on issue (+8.0m options)	105m
Market Capitalisation	A\$114m
Cash (31 st March 2021)	A\$7.1m
Revenue & other income – FY20	A\$3.0m
Net cash burn – FY20	A\$1.6m
Directors Shareholding	22%



Board of Directors



Terry Sweet FAICD, Chairman

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 Managing Director for 4 years, Western Biotechnology Ltd, Heartlink Ltd, and Scientific Services Ltd.



Dr Richard Lipscombe PhD (London), MA (Oxon), 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.



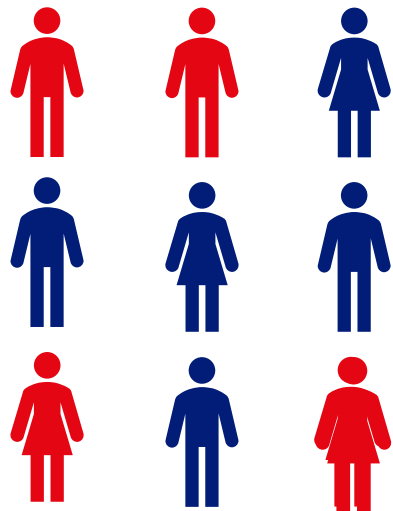
Paul House GAICD, BCommerce (UWA), Non-Executive Director

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.

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

PromarkerD

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
- **Patients ultimately require dialysis and/or a kidney transplant**



Diseased Kidney

PromarkerD

- 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 DKD

High Statistical Performance



Peer reviewed publications – Clinical & analytical validity proven (Sensitivity 86%)

Big Pharma Collaboration



Janssen (J&J) - global multi-centre clinical study - assessing DKD treatment options

Therapeutic Treatments Available



SGLT2-inhibitor class drugs (gliflozins) improve PromarkerD risk scores – Complementary Diagnostic (CDx) opportunity [drug class used for type 2 diabetes & recently approved as new treatment for DKD]

Simple Technology Platform PromarkerD Immunoassay ready



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

Reimbursement



Engaged industry leading consultants to ensure payment coverage in the USA & obtain a unique US reimbursement code: Economic health benefit demonstrated

Regulatory Approvals - ongoing



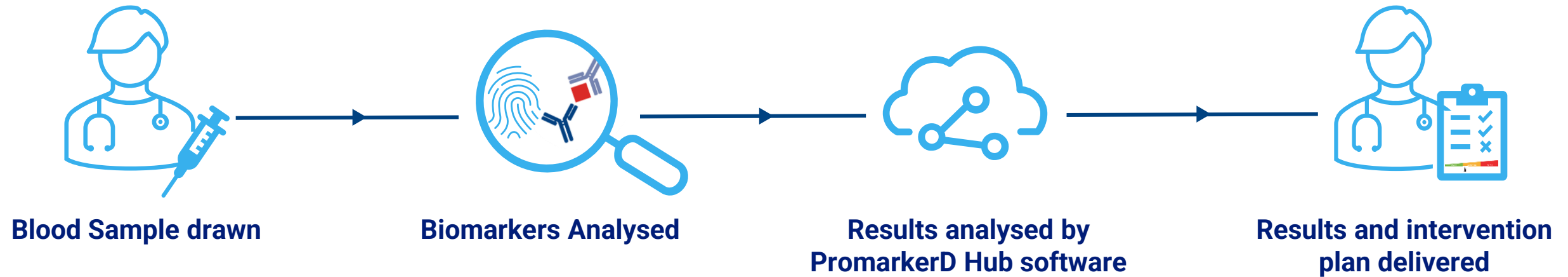
Engaging with partners and national regulators
[US sales to utilise the LDT pathway with CLIA laboratories, prior to FDA approval]

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
- medium risk
- high risk

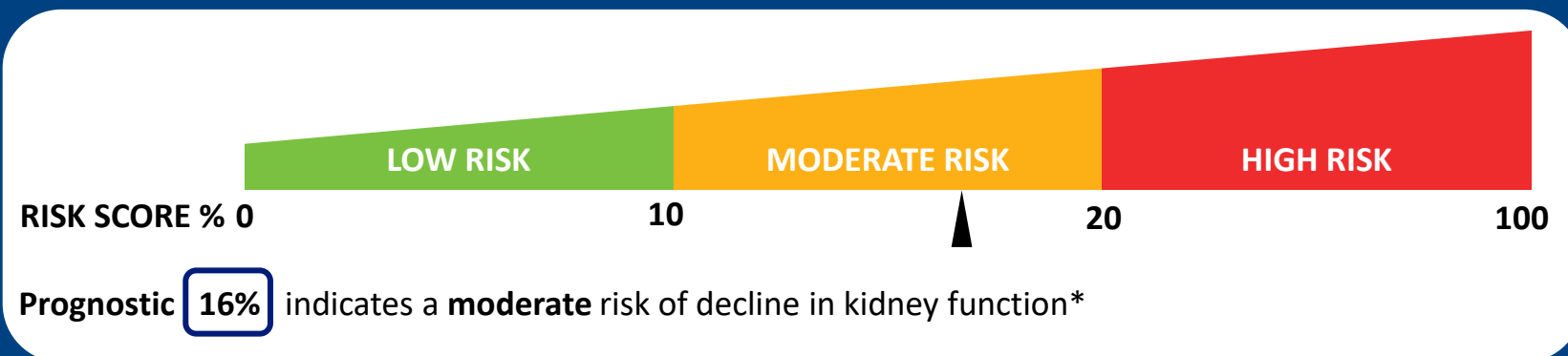
Clinician delivers results to patient

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
- Utilisation of therapeutic drugs

Test every 3-6 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 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)]

Janssen collaboration stage 2 – Assessed the drug treatment effect of canagliflozin versus placebo on PromarkerD risk scores in 2,008 patients; no 'incident DKD' at baseline; 3 year study (from the completed CANVAS clinical trial):

Aim: Do 'at-risk' patients continue to decline, or stabilize, or recover?

Study results: Canagliflozin significantly lowered PromarkerD DKD risk prediction scores

- Across all participants:
 - Patients **on drug** had **decreased mean PromarkerD scores** over the study (Δ score: -1.0%; $p=0.038$),
 - Patients **on placebo** had **increased mean PromarkerD scores** over the study (Δ score: 3.9%; $p<0.001$)
- By PromarkerD risk category, **patients with high-risk scores** at baseline:
 - Patients 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



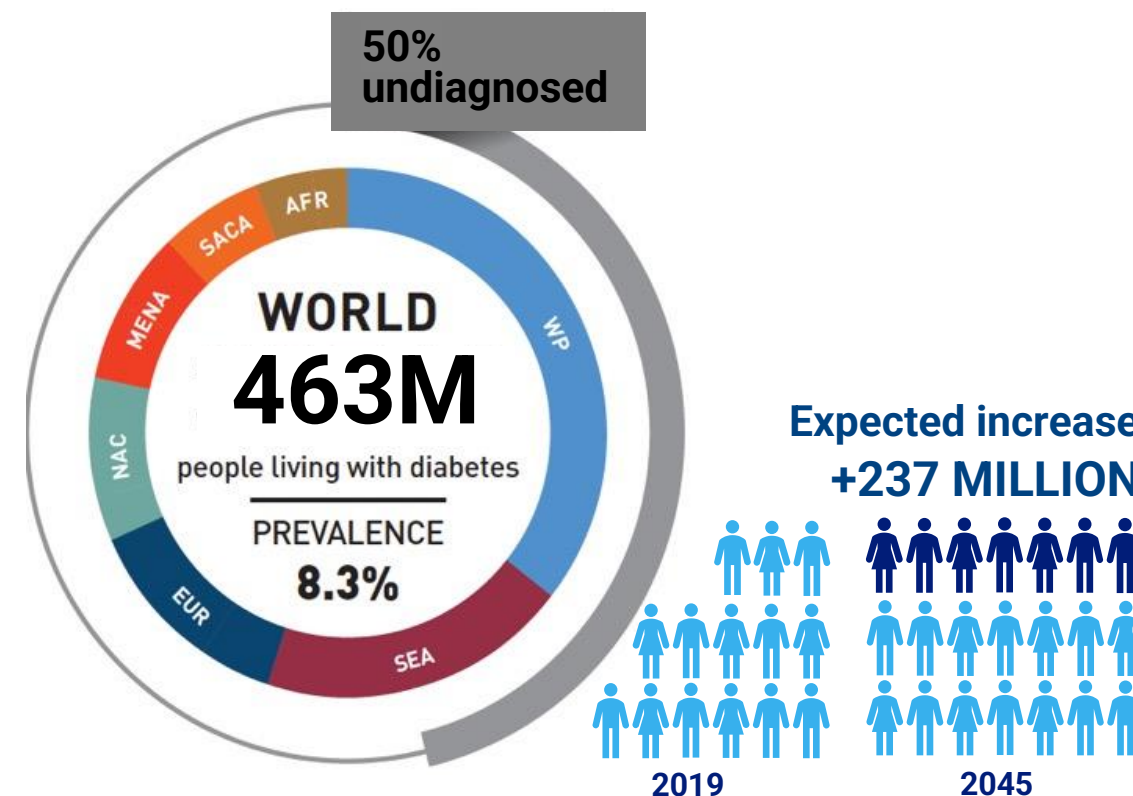
New DKD treatment options identified

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	Granting	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 extended to cover 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 (CDSL)



Market assumptions

- Patent family covers 332m diabetics¹
- **Test is performed once per year per patient on average**
Standard of care: High-risk patients tested every 3 months; Low-risk every year
- **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™



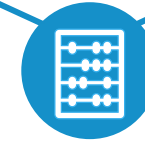
Laboratory conducts tests & submits raw
data to PromarkerD hub



Laboratory pays PIQ a royalty per
test



Immunoassay kits
manufactured and supplied
to laboratory



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

Recent Licensing Transactions

Italy

- Licence with Medical Horizons SRL for immunoassay test
- 3.7m type 2 diabetics (1-in-12)
- Test registered for use with Italian Ministry of Health
- Sales expected Q3 CY21 (delayed by COVID-19)

Israel

- Licence with Zotal Ltd for immunoassay test
- 0.6m type 2 diabetics (1-in-8)
- Product registration expected Q4 CY21

Targeted Licensing Transactions

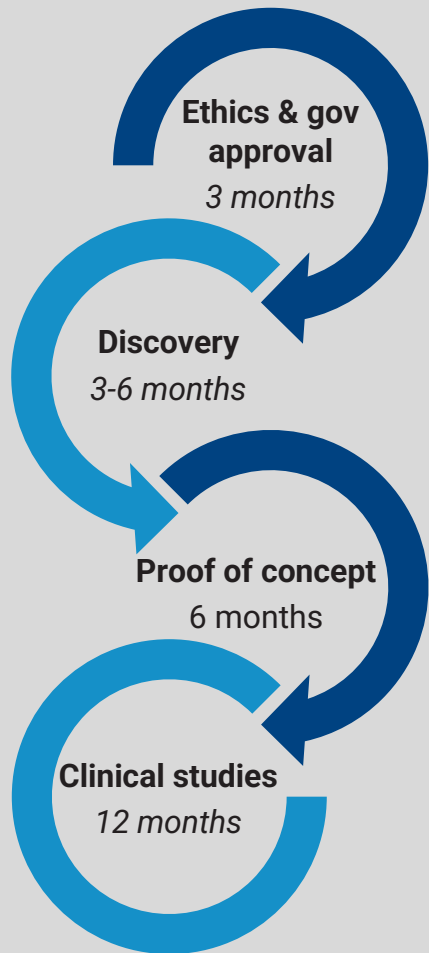
United States

- Discussions ongoing with multiple national/global US diagnostic companies

Europe

- Actively targeting potential partners in key European jurisdictions

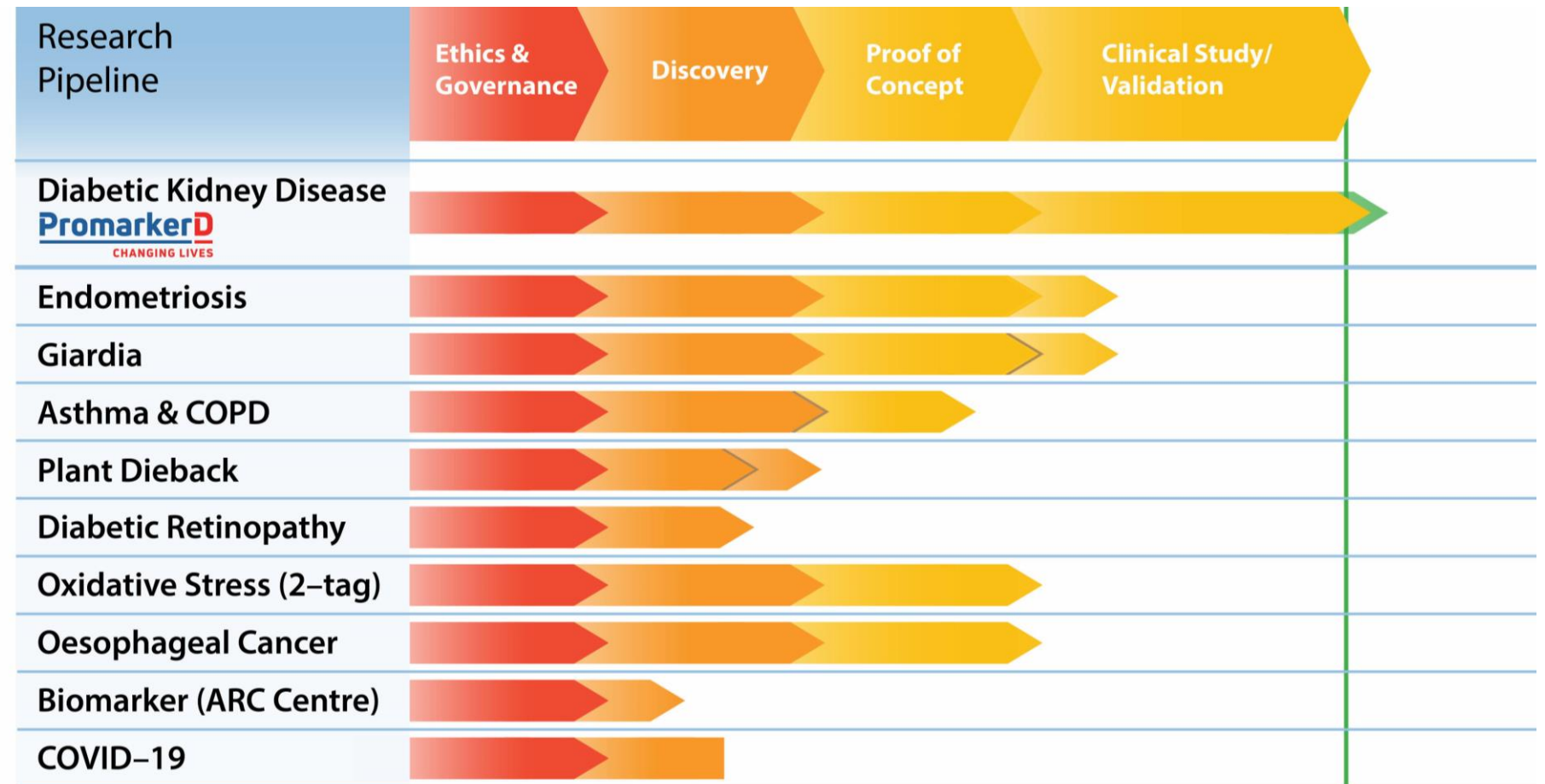
The Promarker™ Research Pipeline & Timeline



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



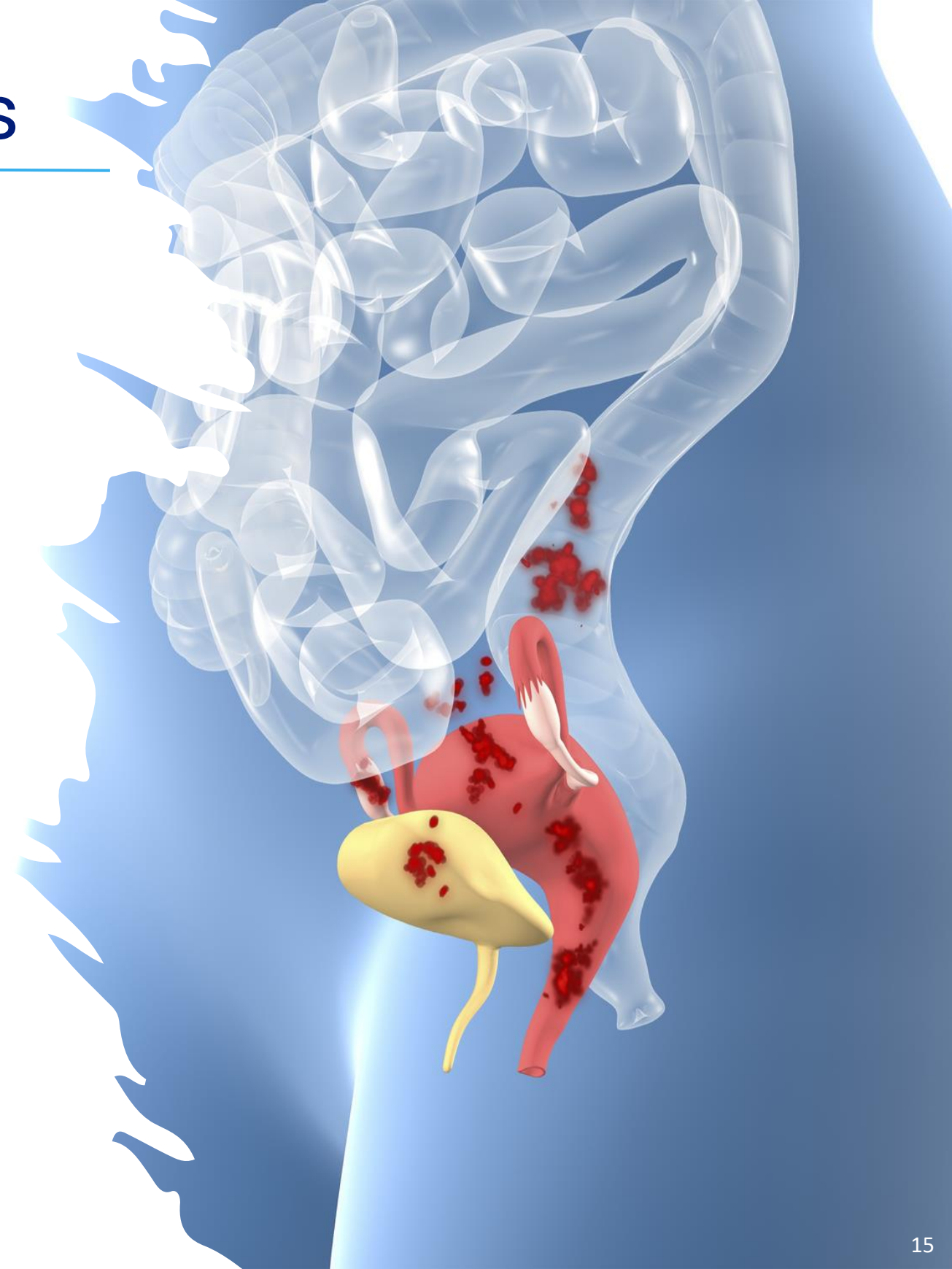
In Development: Endometriosis

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 over AU\$10 billion a year – Global opportunity significantly higher**

Promarker™ for Endometriosis

- Newly identified biomarkers via the Promarker™ platform provide breakthrough in the effort to create a world-first test simple blood sample test for endometriosis
- Proof of concept study performed on 54 women returned statistically significant results
- Patent filed for new invention
- Finalising an agreement to access a large patient cohort for the clinical validation study





ASX: PIQ

Promarker™ Timeline & Upcoming Milestones

Two-year targets and achievements (2019 & 2020)

November 2018

Proteomics enters PromarkerD collaboration with US big pharma Janssen Pharmaceuticals

September 2019

PromarkerD immunoassay development completed & test validated

September 2019

PromarkerD clinical validation results published

February 2019

Proteomics commences manufacture of PromarkerD as immunoassay (IVD)

November 2019

CE Mark for PromarkerD predictive test for diabetic kidney disease

March 2020

Proteomics patents biomarkers for diagnosis of endometriosis

January 2020

PromarkerD software algorithm receives CE Mark

April 2020

CE Mark for PromarkerD immunoassay Kit

June 2020

Big pharma (Janssen) clinical study validates PromarkerD kidney test

9 October 2020

Partnership with QIMR Berghofer Institute targets oesophageal cancer

16 October 2020

First distribution agreement for PromarkerD immunoassay - Italy

12 Nov 2020

Second distribution agreement for PromarkerD immunoassay - Israel

2021

16 July 2021
Successful results from Stage 2 Janssen study

targets

Additional Licensing deals for PromarkerD with diagnostic, pharmaceutical, or services providers

Manufacturing scale up

Reimbursement (Medicare) Code in the USA

New results from the PromarkerD diagnostics pipeline – e.g. Endometriosis, Giardia, 2-Tag, Lung disease

First Sales of PromarkerD immunoassay

FDA regulatory submission in the USA

2021/22 Value Inflection Points



Exceptional Global Opportunity






- Cutting-edge technology & proven in-house diagnostics platform
- PromarkerD test de-risked, patented and rolling-out in easy-to-use, low cost format
- Scalable licensing model with high margins and accessible to diverse range of diagnostic providers
- Deepening pipeline of potential globally significant tests

Share Price Catalysts 2021/22

Milestone	2021	Sep'Q	Dec'Q	Mar'Q	CY'22	Impact
PromarkerD						
Licensing Deals US & EU		█				Drive global uptake and future revenue
First Sales in Europe		█				Drive revenue
US/EU Manufacturing		█				Required for US sales & Regulatory
Janssen Stage 2 Results		█				Drive industry awareness & market demand
FDA Regulatory Approval					█	Build user confidence in product & assist second phase of test roll-out
Regulatory Approvals (other)		█				Assist regional roll-out of test
US Reimbursement Code		█				Secures payer approval & market demand
Promarker™						
Endometriosis		█				New first-in-class diagnostic test/Validates pipeline
Diagnostics pipeline updates		█				Potential proof of concept results/new IP
Analytical Services						
New Contracts		█				Off-set cash burn & engages potential future partners

Peer Comparison



	Stock Code	Company Focus	Market Capitalisation	Share Price	1HF Y21 Revenue	1HF Y21 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\$1.52Bn	970p & US\$27.00	N/A	US\$9.3m loss
	AnteoTech ADO.ASX	Develops, commercialises, manufactures and distributes products for the life sciences research, diagnostics and medical device markets	A\$469m	A\$0.24	~A\$0.6m	A\$1.5m loss
	Bard1 Life Sciences BD1.ASX	Early stage in-licensed IP for various cancer diagnostics.	A\$150m	A\$1.85	~A0.2m	A\$3.3m loss
	Rhythm Biosciences RHY.ASX	Pre-commercialisation proteomics derived diagnostic test for colon cancer licensed from CSIRO.	A\$191m	A\$0.94	N/A	A\$2.0m 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\$114m	A\$1.08	A\$0.9m	A\$1.8m loss

Source: Bloomberg, company filings. Market data as at 16 July 2021, exchange rates of AUDGBP 0.54 and AUDUSD 0.74

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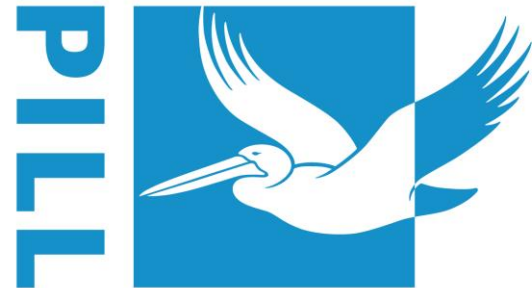
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