

**Proteomics International**

LABORATORIES LTD

**ASX Release**

**26 May 2022**

**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 the Jefferies MedTech & Biotech virtual summit being held 26 and 27 May 2022.

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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ASX: PIQ

# Proteomics International

LABORATORIES LTD

## Jefferies MedTech & Biotech Virtual Summit

### Investor Presentation

**26 May 2022**

**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)
- 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

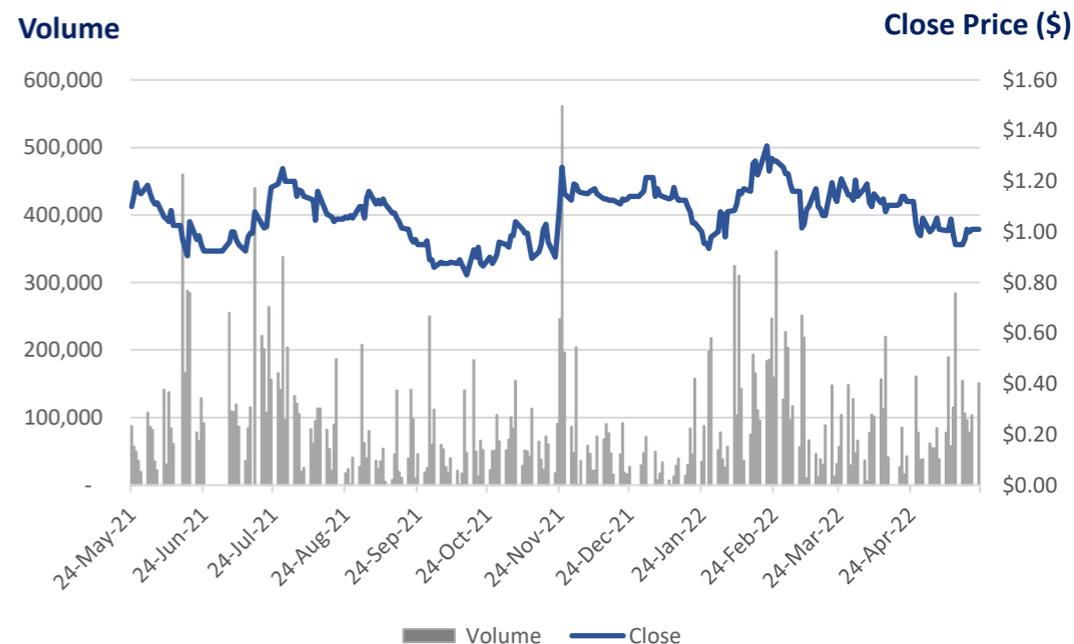
- Growing demand from industry for specialised analytics
  - Thriving sectors of pharmacokinetic (PK) testing and biosimilars
- State-of-the-art capabilities with >\$4m invested in cutting-edge facility
- Revenue partially offsets the cash burn from R&D and product development

## Financial & Corporate

- Senior management team expanded (Jun 21) + Board renewal (Nov 21)
- R&D tax incentive rebate of ~A\$1.5 million to be received in Q4 CY22
- Awarded \$0.4m manufacturing funding by MTPConnect (May 22)
- Implementing expansion strategies to accelerate growth

## Corporate Snapshot – 23/05/2022

ASX code	PIQ
Share Price	A\$1.01
Shares on issue (+8.4m options)	106m
Market Capitalisation	A\$107m
Cash (31 March 2022 + ~\$1.5m R&D to be received Q4 CY22)	A\$3.3m
Revenue & other income – FY21	A\$3.0m
Net cash burn – FY21	A\$2.9m
Directors Shareholding	19.6%



# 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.



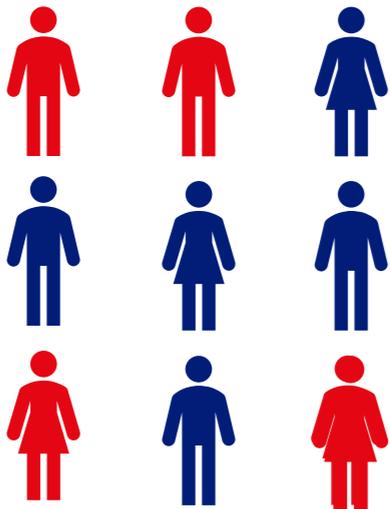
**Dr Robyn Elliott** PhD Inorganic Chemistry (Monash), BSc(Hons) Chemistry (Monash), Non-Executive Director

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).

# 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

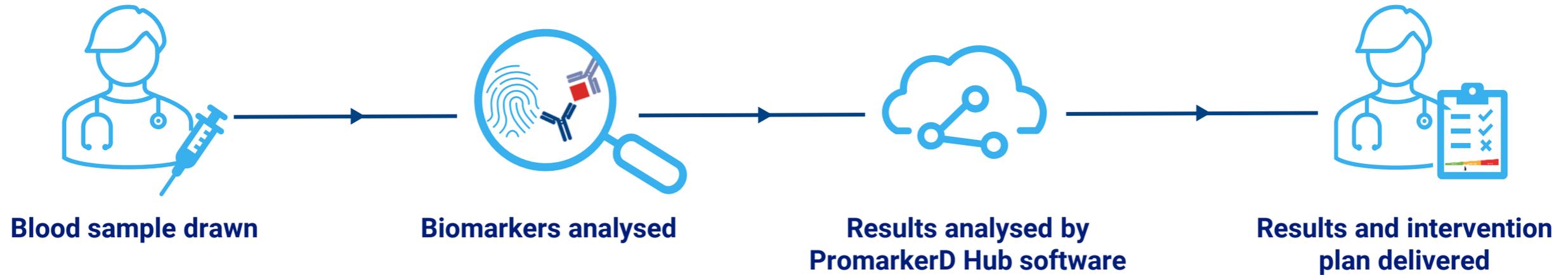
# PromarkerD is Revenue Ready



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

<b>Enormous Market</b>	✓	537m adults have diabetes globally: 1-in-3 currently have diabetic kidney disease (DKD)
<b>High Statistical Performance</b>	✓	Peer reviewed publications – Clinical & analytical validity proven (Sensitivity 86%); PromarkerD significantly outperforms current standard of care
<b>Big Pharma Collaboration</b>	✓	 (J&J) – global multi-centre clinical study - assessing PromarkerD vs treatment options
<b>Therapeutic Treatments Available</b>	✓	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]
<b>Simple Technology Platform</b> - PromarkerD Immunoassay	✓	Clinical pathology laboratories can easily introduce the PromarkerD immunoassay as an IVD kit or LDT
<b>Regulatory Approvals</b>	✓	CE Mark (Europe) registration received for the PromarkerD Immunoassay; Secured ISO 13485 certification for the manufacture of medical devices
<b>Manufacturing scale-up</b>	●	Specialist companies working to enable reagent supply and ISO 13485 certified kit manufacture
<b>Reimbursement</b>	●	Identified pathway to obtain a unique reimbursement code & payment coverage in the USA: Economic Health Benefit & Clinical Utility demonstrated
<b>Regulatory Approvals - ongoing</b>	●	Engaging with partners and national regulators [US sales to utilise the Lab Developed Test (LDT) pathway with CLIA laboratories, prior to FDA approval]
<b>Generate Sales Revenue</b>	●	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

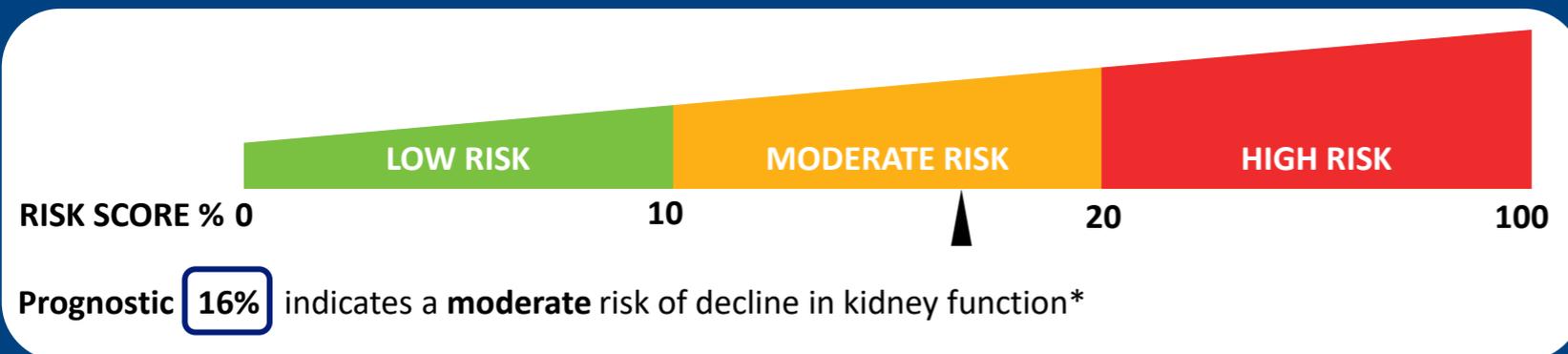
Clinician delivers results to patient

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
<b>Low Risk</b>	<ul style="list-style-type: none"> <li>Standard diabetes management</li> </ul>	<b>Test Annually</b>
<b>Moderate Risk</b>	<ul style="list-style-type: none"> <li>More frequent monitoring</li> <li>Optimisation of lifestyle</li> <li>Review of glycemic targets and management</li> <li>Review non-glycemic risk factors</li> <li>Avoidance of potentially nephrotoxic drugs</li> </ul>	<b>Test every 6 months</b>
<b>High Risk</b>	<ul style="list-style-type: none"> <li>Very close monitoring</li> <li>Intensive management strategies based on those for 'Moderate risk' above</li> <li>Utilisation of therapeutic drugs</li> </ul>	<b>Test every 3 months</b>

\*as defined by incident diabetic kidney disease (eGFR <60ml/min/1.73m<sup>2</sup>) in the next four years. Note: if eGFR level at the time of the test is already <60ml/min/1.73m<sup>2</sup>, 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 ( $\Delta$  score: -5.6%;  $p < 0.001$ )
- Patients **on placebo remained high** ( $\Delta$  score: 3.2%;  $p = 0.17$ ) (Time\*TRT  $p = 0.002$ ) [ADC (Aug 2021)]

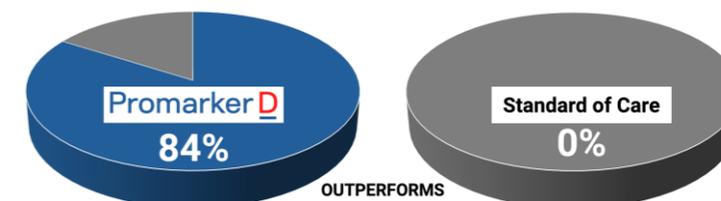
**Conclusion:** PromarkerD can identify 'at-risk' patients who are asymptomatic for DKD, with canagliflozin offering a potential treatment that can improve their renal risk profile



### 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)]

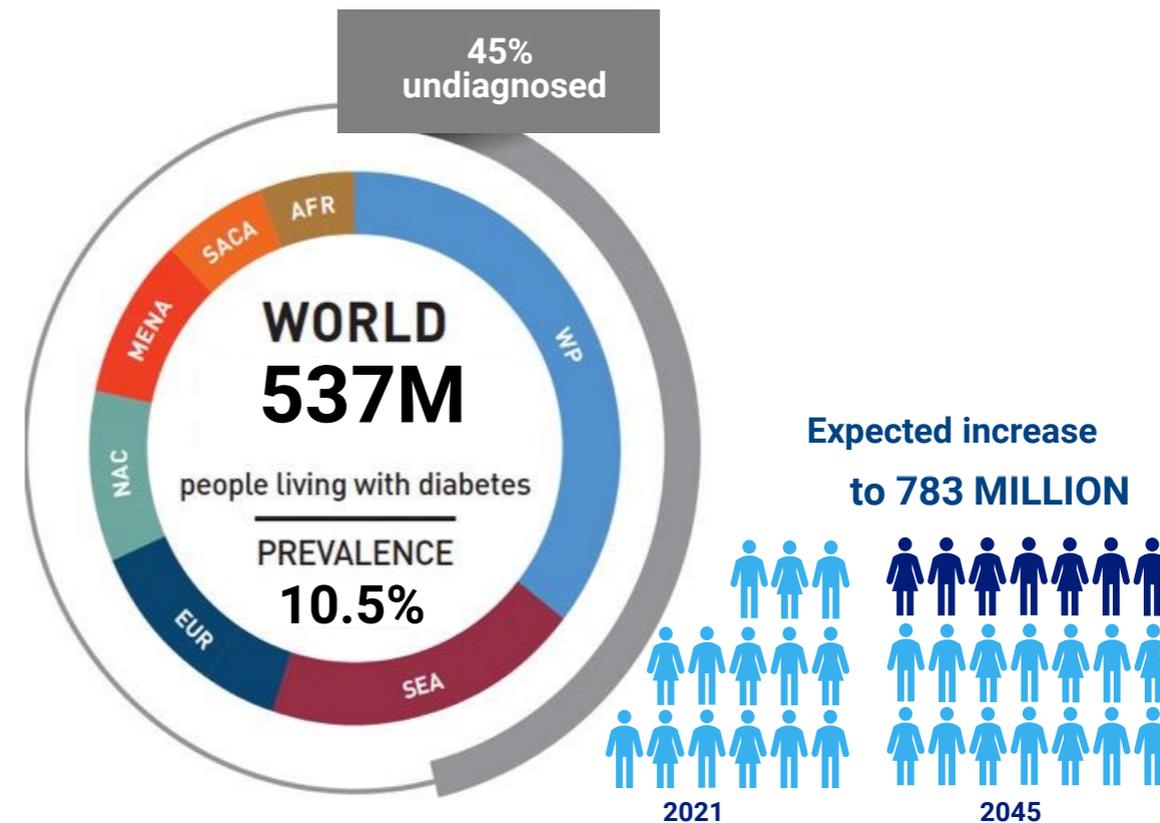


# PromarkerD Market Opportunity

## Diabetes incidence and Patent portfolio

Country	Patent/Application No	Patent Status	No. Diabetics <sup>1</sup>
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 <sup>2,3</sup>	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 <sup>2,4</sup>	US 9,146,243	Granted	32,215,300
			<b>~340 million Total</b>

1. International Diabetes Federation (IDF) Atlas 10<sup>th</sup> 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 diabetics<sup>1</sup>
- **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 1H 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 1H CY22 (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 companies

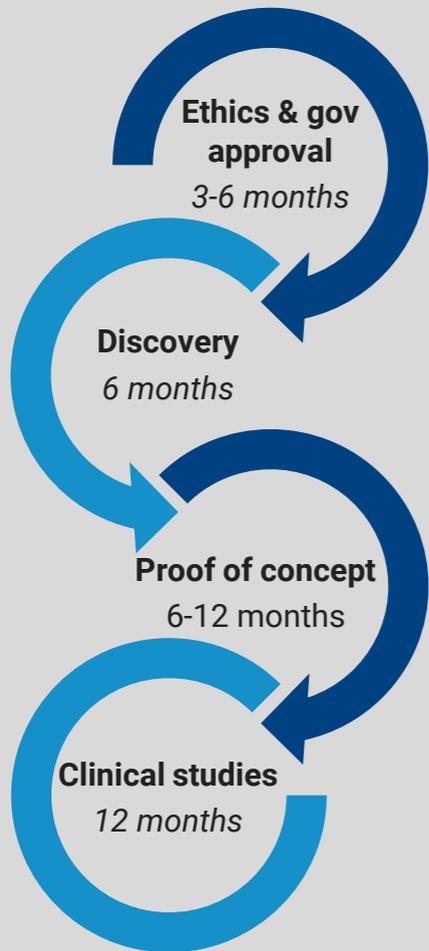
### RoW

- Actively targeting potential partners in key global jurisdictions



# Diagnostics Pipeline

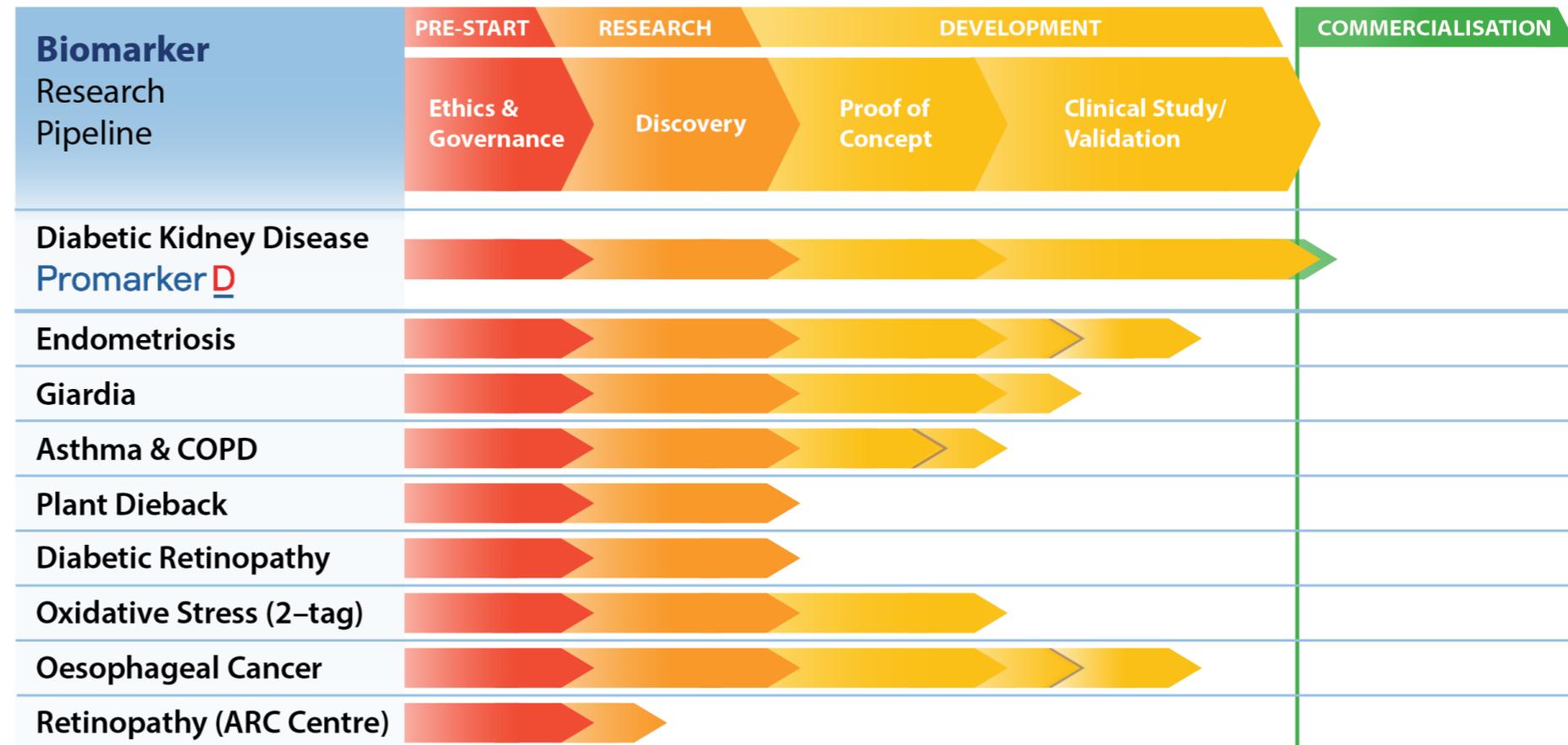
## The Promarker™ Research Pipeline & Timeline



## 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



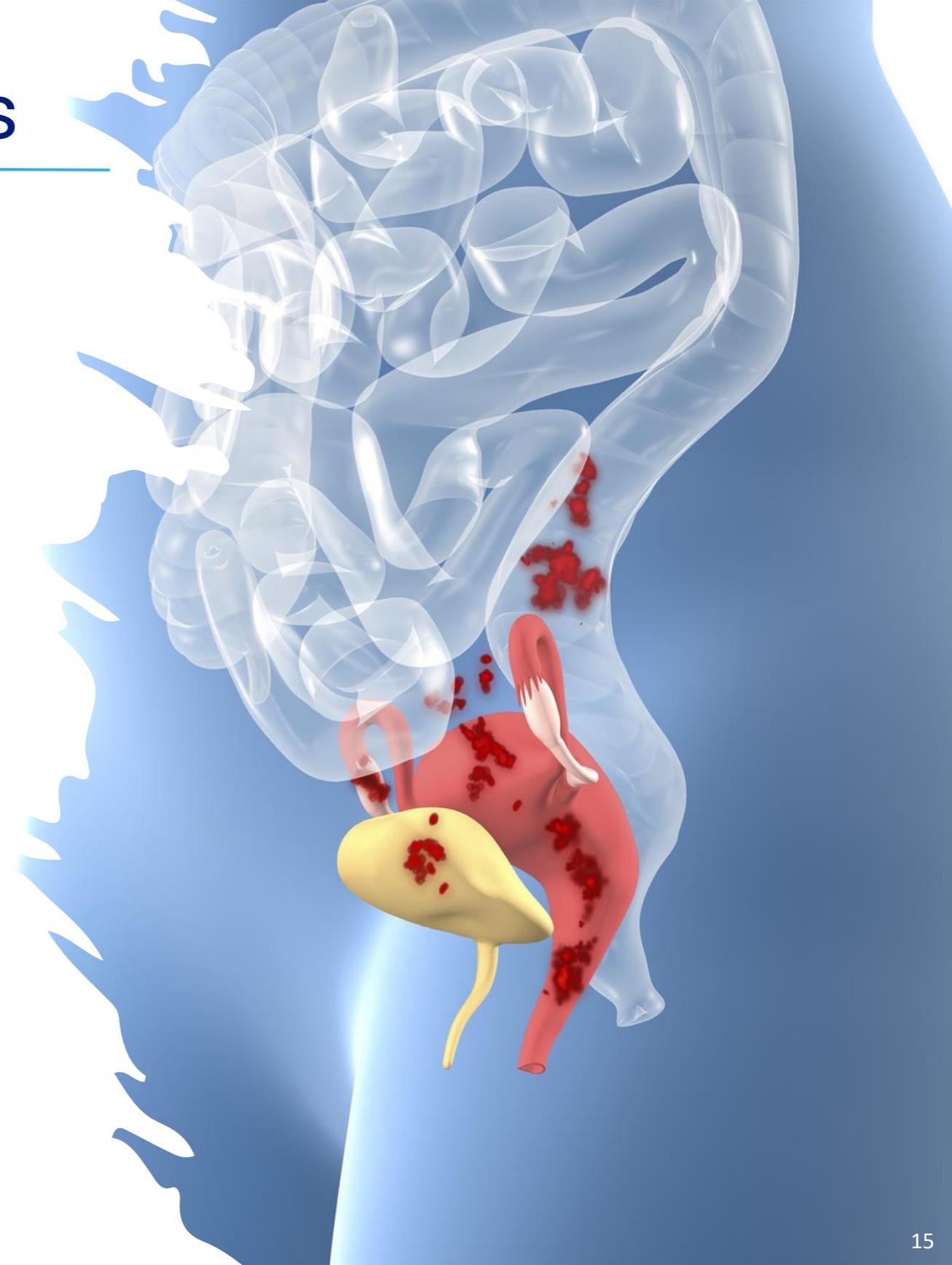
# In Development: Endometriosis

## 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 over AU\$10 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 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 Q2 CY22**





# 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 2022

Milestone	Qtr	Jun'22	Sep'22	Dec'22	Impact
<b>PromarkerD</b>					
Licensing Deals		■	■	■	Drive global uptake and future revenue
First Sales		■	■		Drive revenue
ISO 13485 Manufacturing Site		■			Ability to supply global markets
US Reimbursement		■	■	■	CPT PLA code & Payor coverage
Regulatory Submissions & Approvals		■	■	■	Build user confidence in product & assist of global roll-out
<b>Promarker™</b>					
Endometriosis Study Results		■			New first-in-class diagnostic test
Diagnostics Pipeline Updates		■	■	■	New IP (validation & proof of concept results)
<b>Analytical Services</b>					
New Contracts		■	■	■	Off-set cash burn & engages potential future partners

# Peer Comparison



ASX: PIQ

	Stock Code	Company Focus	Market Capitalisation	Share Price	FY21 Revenue	FY21 Net Profit/Loss
 <b>Renalytix AI</b>	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\$203m	160p	~A\$2.1m	~A\$43m loss
 <b>Rhythm Biosciences</b>	RHY.ASX	Pre-commercialisation proteomics derived diagnostic test for colon cancer licensed from CSIRO.	A\$247m	A\$1.155	Nil	A\$6.6m loss
 <b>AnteoTech</b>	ADO.ASX	Develops, commercialises, manufactures and distributes products for the life sciences research, diagnostics and medical device markets	A\$219m	A\$0.11	A\$0.9m	A\$6.2m loss
 <b>Lucid Diagnostics Inc</b>	LUCD.US	Commercial-stage, cancer prevention medical diagnostics company with a DNA test (via LDT) for oesophageal cancer.	~A\$119m	US\$2.23	~A\$0.3m (9 months to 30 Sep 21)	~A\$23m (9 months to 30 Sep 21)
 <b>Innoviq Ltd</b> (renamed from Bard1)	IIQ.ASX	Early stage in-licensed IP for various cancer diagnostics.	A\$52m	A\$0.565	A\$0.5m	A\$12.3m loss
 <b>Proteomics International Laboratories</b>	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\$107m	A\$1.01	A\$1.5m	A\$2.9m loss

Source: Company filings. Market data as at 23 May 2022, exchange rates of GBP:AUD 1.7 and USD:AUD 1.40

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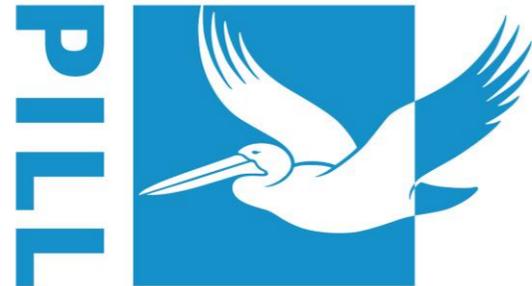
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