

**Proteomics International**  
LABORATORIES LTD

# Investor Presentation

26<sup>th</sup> August 2020

ASX: PIQ

BUILDING A GLOBAL  
DIAGNOSTICS BUSINESS

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# CORPORATE OVERVIEW



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**Proteomics International Laboratories Ltd (ASX: PIQ) is a medical technology company at the forefront of predictive diagnostics and bioanalytical services**

## DIAGNOSTICS

### PromarkerD

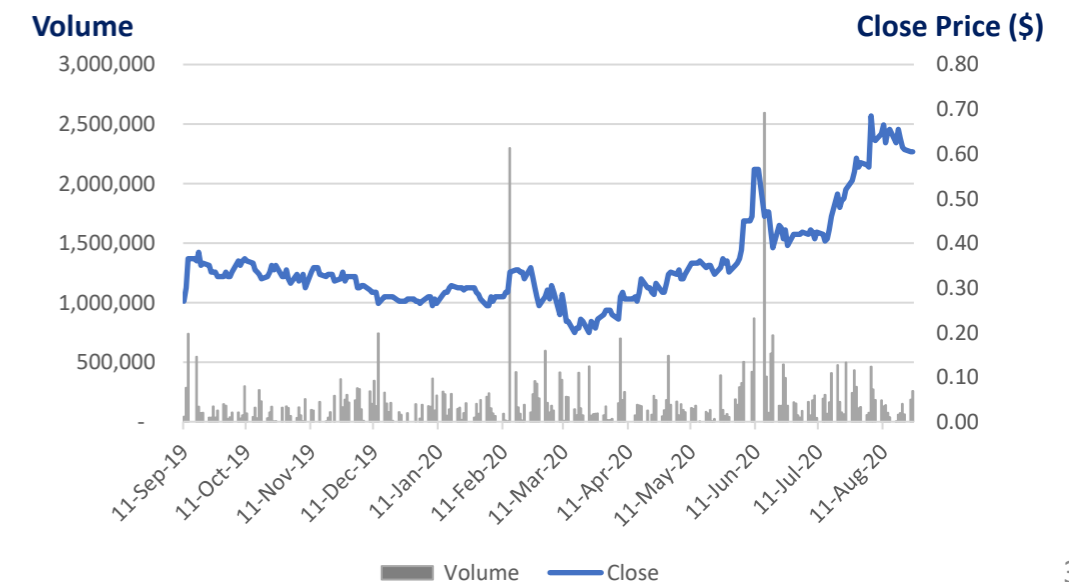
- Predictive test for early identification of diabetic kidney disease (DKD)
- Accurately predicts four years prior to typical clinical diagnosis
- Patented, cost-effective, easy to use technology
- Early diagnosis can delay disease onset, resulting in significant benefits to the patient and healthcare systems
- Additional tests in the pipeline – Endometriosis, COVID-19, Gastro, Oxidative Stress, 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

## CORPORATE SNAPSHOT – 25/8/2020

ASX code	PIQ
Share Price	\$0.605
Shares on issue (+ 4m options)	92m
Market Capitalisation	\$55.6m
Enterprise Value	\$52m
Cash	\$2.4m (+\$1.2m R&D tax)
Cash Runway	> 12 months
Revenue & other income – FY19	\$2.7m
Directors Shareholding	25%



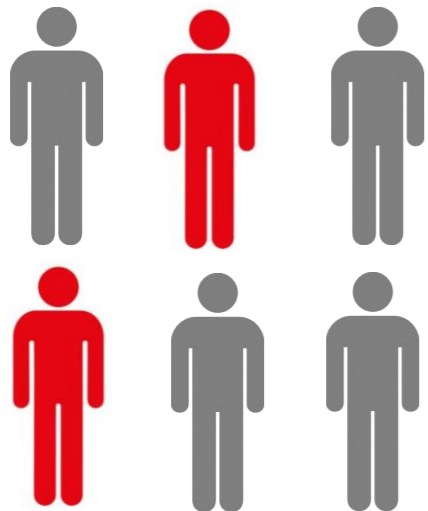


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# PROMARKER – PLATFORM TECHNOLOGY



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 to formulate commercial diagnostic tests

# PromarkerD



**PREDICTIVE TEST FOR DIABETIC KIDNEY DISEASE**

# BUILDING A GLOBAL DIAGNOSTICS BUSINESS



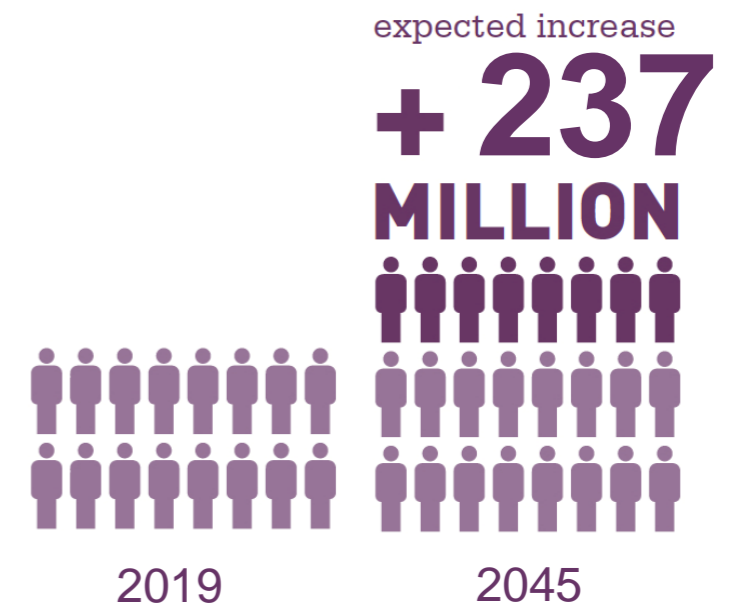
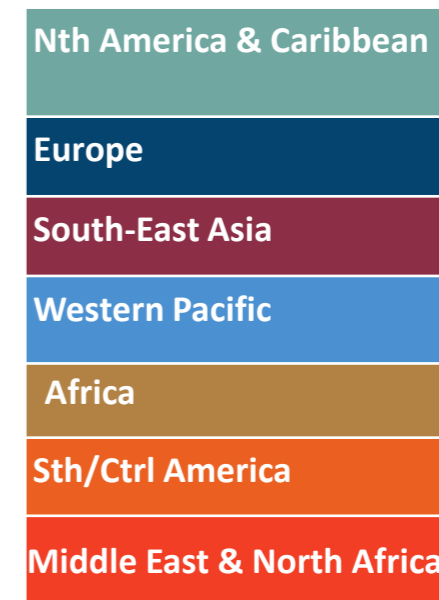
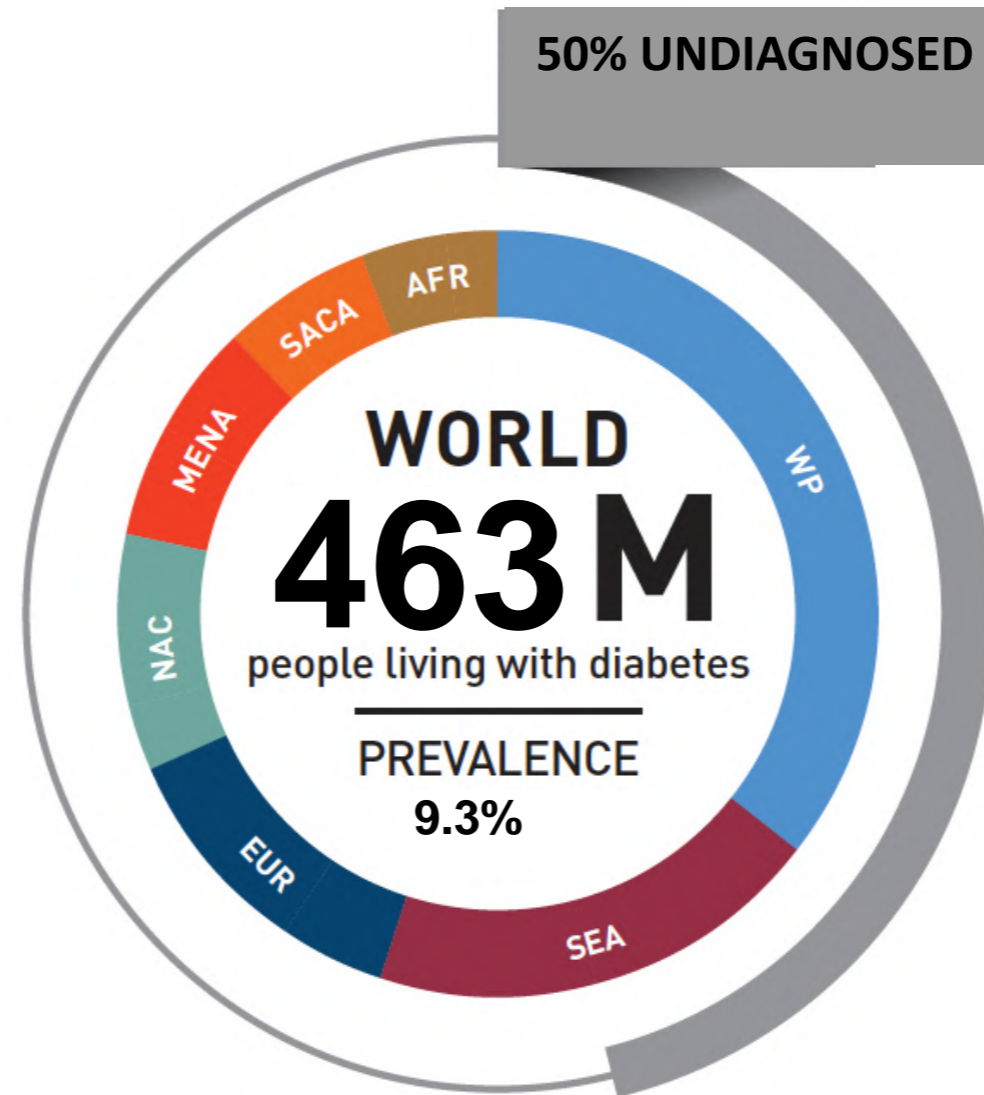
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**PromarkerD is revenue ready and Proteomics International is currently in discussions globally to bring the test to market**

<b>Simple Technology Platform</b> PromarkerD Immunoassay ready	✓	Certified laboratories can easily introduce the PromarkerD immunoassay as an LDT
<b>High Statistical Performance</b>	✓	Peer reviewed publications - Analytical & Clinical validity evidence
<b>Regulatory Approval in Europe</b>	✓	CE Mark registration received for the PromarkerD Immunoassay
<b>Big Pharma Interested</b>	✓	Collaboration with Janssen - global multi-centre clinical study
<b>Enormous Market</b>	✓	463m adults have diabetes globally - 1 in 3 currently have DKD
<b>Therapeutic Treatments Available</b>	✓	SGLT2 inhibitor class drugs with renal protection approved for type 2 diabetes treatment
<b>Reimbursement</b>		Engaged industry leading consultant to obtain a unique US reimbursement code

# MARKET SIZE?

- Global IVD market worth US\$67 billion in 2019, projected to reach \$91 billion by 2027
- Proteomics market valued at US\$24 billion in 2017, expected to reach \$72 billion by 2025 at CAGR of 14.5%
- Driven by developments in personalized medicine and identification of biomarkers for disease diagnosis



Targeting Type 2 Diabetes (~90% of diabetics)



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# A MAJOR OPPORTUNITY

## THE PROBLEM

- ▶ 463 million people have diabetes
- ▶ 1 in 3 diabetic adults currently have chronic kidney disease

- ▶ There are no early symptoms of diabetic kidney disease - **Kidney function can fall below 15-20% with no symptoms**
- ▶ The current standard-of-care tests cannot predict the onset of diabetic kidney disease
- ▶ Diabetic kidney disease leads to end stage renal disease (ESRD) which requires dialysis (US\$72,000 p.a.) or kidney transplant
- ▶ **Total cost of diabetic kidney disease = US\$50 billion per year in USA alone**



## THE SOLUTION

PromarkerD: A predictive test for diabetic kidney disease

- ▶ PromarkerD can **predict** the onset of disease **before** clinical symptoms appear
- ▶ ***Doctors can then prescribe an early therapeutic treatment to slow or stop the onset of disease***



# PromarkerD PLATFORMS



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## PREDICTIVE TEST for DIABETIC KIDNEY DISEASE

PromarkerD assay can be readily ported to different pathology lab platforms



Immunoassay Kit



Laboratory Developed Test - LDT



Automated Immunoassay

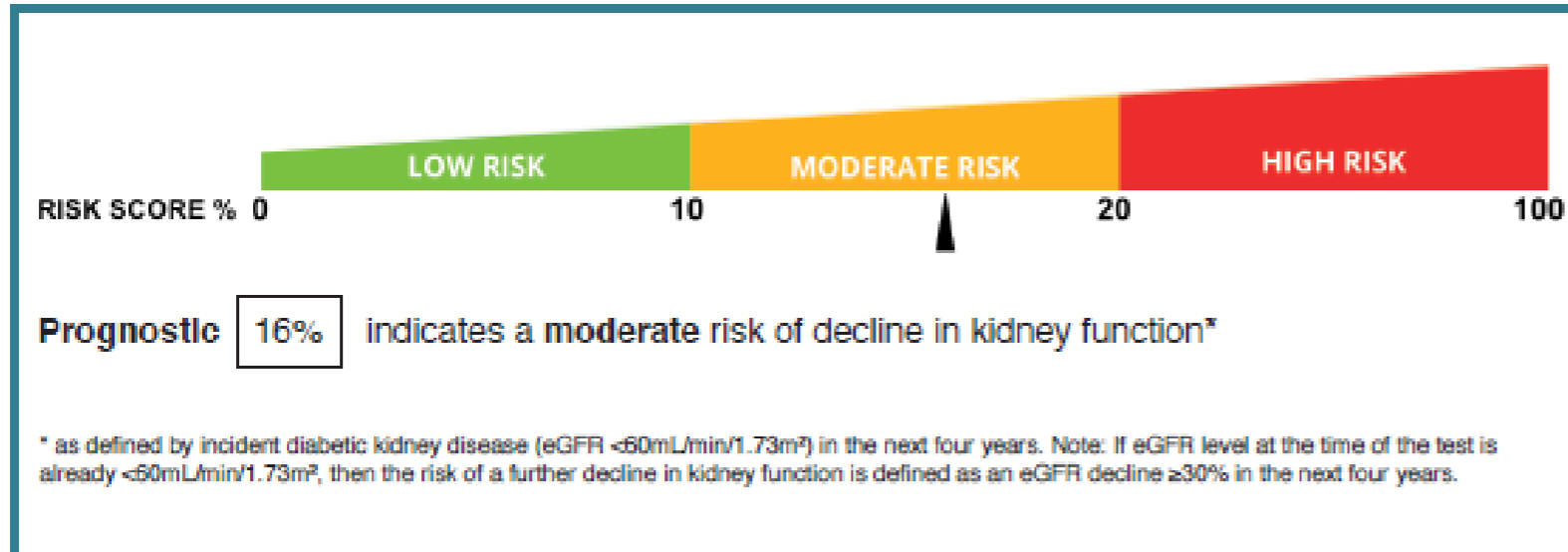
- **Cost-effective, easy-to-use** technology platforms
- **Regulatory approval** – European CE Mark registered
- In commercial discussions with **pathology laboratories, diagnostics manufacturers, and pharmaceutical companies**



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# PromarkerD IN THE CLINIC

## TEST RESULTS



## PREDICTIVE TEST for DIABETIC KIDNEY DISEASE

PromarkerD patient reports use a traffic light scoring system for optimal performance

A simple blood test that measures three plasma proteins combined with three clinical factors (age, cholesterol, eGFR)

In published clinical studies PromarkerD predicted 86% of otherwise healthy diabetics who went on to develop kidney disease within 4 years

## Result Interpretation

<b>Low Risk</b>	Standard diabetes management; Status tested annually.
<b>Moderate Risk</b>	More frequent monitoring; Optimisation of lifestyle factors; Review of glycemic targets and management; Review of non-glycemic risk factors and their management including blood pressure and lipids; Avoidance of potentially nephrotoxic drugs; Utilisation of therapeutic drugs with evidence of renoprotection; Status tested every 3-6 months.
<b>High Risk</b>	Very close monitoring; Intensive management strategies based on those for 'Moderate risk' above with optimisation of treatments for diabetes and other risk factors. Status tested every 3 months.

Interpretation of Risk Scores (based on recommendations from the ADA DKD Consensus report)



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# TREATMENTS FOR DKD - SGLT2 INHIBITORS

## The GLIFLOZINS

- SGLT2 inhibitors, known as Gliflozins, treat diabetes by helping the kidneys to lower blood glucose levels
- Empagliflozin (Lilly & Boehringer Ingelheim), Dapagliflozin (Astra Zeneca & Bristol-Myers Squibb), and Canagliflozin (Janssen) are class leading approved diabetes treatments
- 30 September 2019, Canagliflozin (Invokana™) became the first drug in 20 years to be approved for the treatment diabetic kidney disease
- The gliflozins all appear to exhibit renal-protective properties and able to reduce the risk of renal failure, dialysis or kidney transplantation for DKD patients
- 2019 drug sales for:
  - **Empagliflozin (Jardiance™) - Est >US\$3 billion\***
  - **Dapagliflozin (Farxiga™) - US\$1.54 billion\***
  - **Canagliflozin (Invokana™) - US\$735 million\***

## COMMERCIAL UPSIDE

- **PromarkerD could become a prognostic test for big pharma companies that are:**
  - promoting an approved treatment - a complementary diagnostic (CDx) will guide patients to their treatment
  - conducting clinical trials - patient populations can be targeted/recruited to enhance overall efficacy (reduce placebo or negative response)
- Potential to capture at risk patients up to 4 years earlier
- Earlier treatment, could mean lower drug doses with lower side-effects and improved drug safety profile, and improved patient outcomes
- Upcoming FDA regulatory approval process should be accelerated by using the Janssen/PromarkerD data

*\*<https://pharmaphorum.com/news/fda-fast-tracks-lilly-boehringer-jardiance-in-chronic-kidney-disease/>*

*\*<https://www.fiercepharma.com/pharma/invokana-win-kidney-patients-could-help-j-j-right-sglt2-ship>*



Proteomics International and Janssen are studying the performance of PromarkerD in predicting decline in kidney function and treatment response in patients from a Janssen completed clinical trial

## STAGE 1 STUDY

- ▶ **PromarkerD validated in global multi-centre study of 3,000 people**
  - Results co-presented at the 80<sup>th</sup> Scientific Sessions of the American Diabetes Association (ADA), 13 June '20
  - PromarkerD predicted outcomes in the CANVAS trial (CANagliflozin CardioVascular Assessment Study)
  - The results showed that patients predicted by PromarkerD to be at high-risk of chronic kidney disease were 13.5 times more likely than the low-risk group to develop the disease, with the results showing high statistical significance ( $P = 1.3 \times 10^{-104}$ )
  - The PromarkerD statistics compare favourably against diagnostic & prognostic tests already on the market for other chronic diseases

## COLLABORATION EXPANDED TO STAGE 2

- Janssen elected to expand the collaboration in March 2020
- Stage 2 study to determine if PromarkerD can help assess the effectiveness of canagliflozin as a treatment for diabetic kidney disease
- The additional stages to be completed later in CY2020 & subject to peer review before release
- **Potential for PromarkerD to become a Complementary Diagnostic (CDx) means a PromarkerD test could be used:**
  - upon prescription of drug treatments for diabetes
  - throughout a patient's course of treatment (potentially lifetime) to monitor the ongoing risk of developing chronic kidney disease

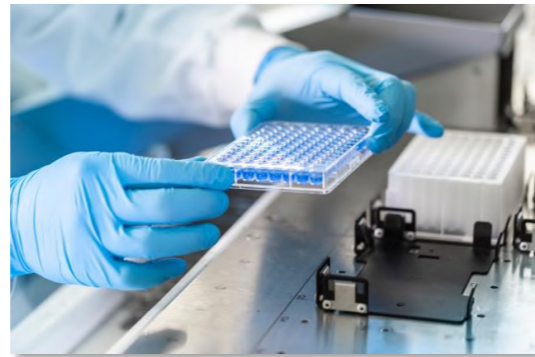


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# ROUTE TO MARKET

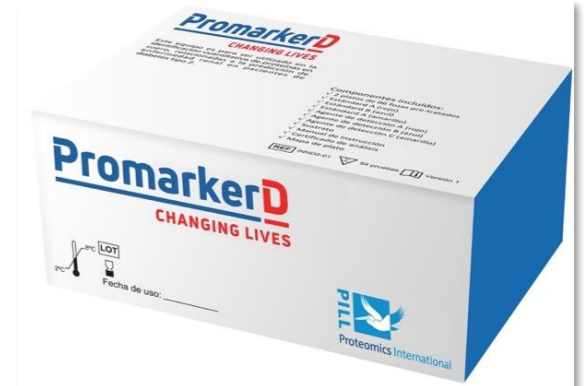
## LABORATORY DEVELOPED TEST (LDT)

- **Immunoassay or Mass spectrometry**
- Tests run via certified laboratories
- The LDT permits fast adoption of a new test in advanced markets
  - **Fast regulatory pathway**
  - **Builds market demand**



## IN VITRO DIAGNOSTIC TEST (IVD)

- **Immunoassay kit or automated machine platform**
  - both platforms standard to pathology laboratories
- Assay validated
- CE Mark approved
- **- Ready to commercialise**



## Example of out-licensing model for a Pathology Laboratory

- PIQ licences test to be run in certified lab via Immunoassay (e.g. US) or Kit (e.g. EU)
- PIQ facilitates the production and delivery of reagents to laboratory
- Lab conducts tests using reagents and sends results (raw data) to the PromarkerD hub (server)
- PromarkerD algorithm calculates risk score (Low, Moderate, High) and returns report to lab
- Lab pays PIQ a royalty (5-15%) per test



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# MARKET OPPORTUNITY – PromarkerD

## Market assumptions:

- **Test is performed once per year per patient on average** [Standard of care: High-risk patients are tested every 3-6 months; Low-risk every 2 years].
- **Test price of US\$55-\$150** [\$55 is based on use of existing CPT codes for similar analytes to the PromarkerD panel; \$150 is based on stakeholder engagement responses (market access study conducted by independent consultant)].
- **Standard industry royalty rates range from 5-15%**

Country	Patent/ Application No.	Status	Diabetes Prevalence <sup>1</sup>
Australia <sup>2</sup>	2011305050	Granted	1,288,300
Brazil	BR1120130067640	Granting	16,780,800
Canada	2811654	Granted	2,793,500
China	ZL201180053583.9	Granted	116,446,900
Europe <sup>2,3</sup>	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 <sup>2,4</sup>	US 9,146,243	Granted	30,987,900
			<b>332,349,300 Total</b>

<sup>1</sup> International Diabetes Federation (IDF) Atlas 9th Edition 2019 [Age group 20-79 years; Total = Diagnosed (48.7%) + Undiagnosed (51.3%)].

<sup>2</sup> 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)

<sup>3</sup> Covers France, Germany, Italy, Spain, Turkey, and the United Kingdom, which cumulatively have 29.6 million adults with diabetes.

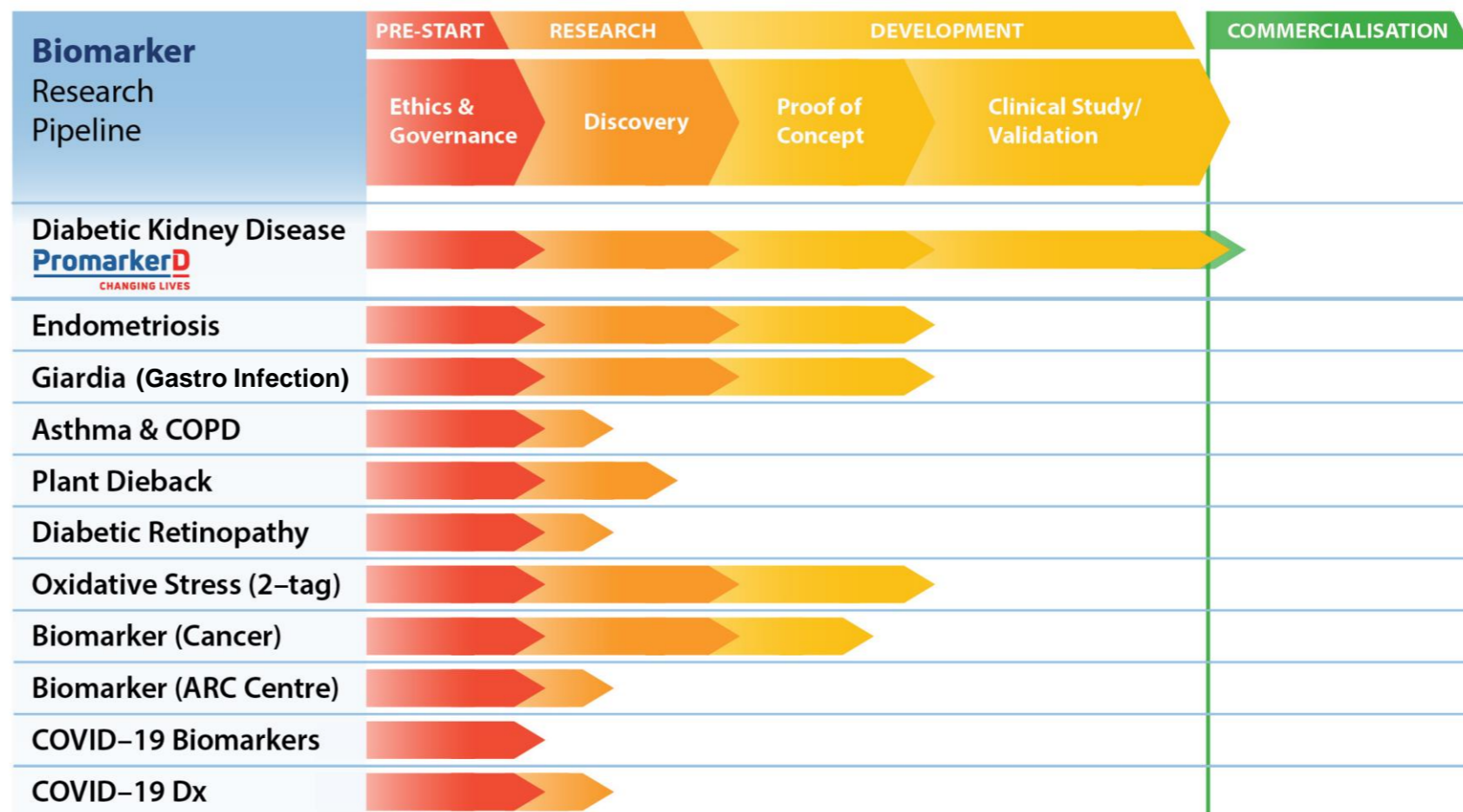
<sup>4</sup> USA patent further extended to cover method for identifying drugs for abnormal kidney function using one of the PromarkerD biomarkers (CD5L).

# DIAGNOSTICS PIPELINE

## FURTHER GLOBAL POTENTIAL IN NEW MARKETS

- ▶ Proteomics endeavours to leverage its Promarker™ Platform to develop and commercialise a suite of diagnostic tests
- ▶ Potential for faster market adoption for a new diagnostic test, post a successful PromarkerD commercialisation
- ▶ Enormous markets and revenue potential

### DIAGNOSTICS RESEARCH AND DEVELOPMENT – THE PROMARKER™ PIPELINE



The Promarker™ research pipeline and typical timeline is:

- Ethics & gov approval (3 months)
- Discovery (3-6 months),
- Proof of concept (6 months)
- Clinical studies (12 months)

# ENDOMETRIOSIS



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## 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 to 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 standard blood sample test for endometriosis
- ▶ Proof of concept study performed on 54 women returned statistically significant results
- ▶ Patent filed for new invention





# COVID-19 DIAGNOSTICS & OXIDATIVE STRESS

## COVID-19 DIAGNOSTICS

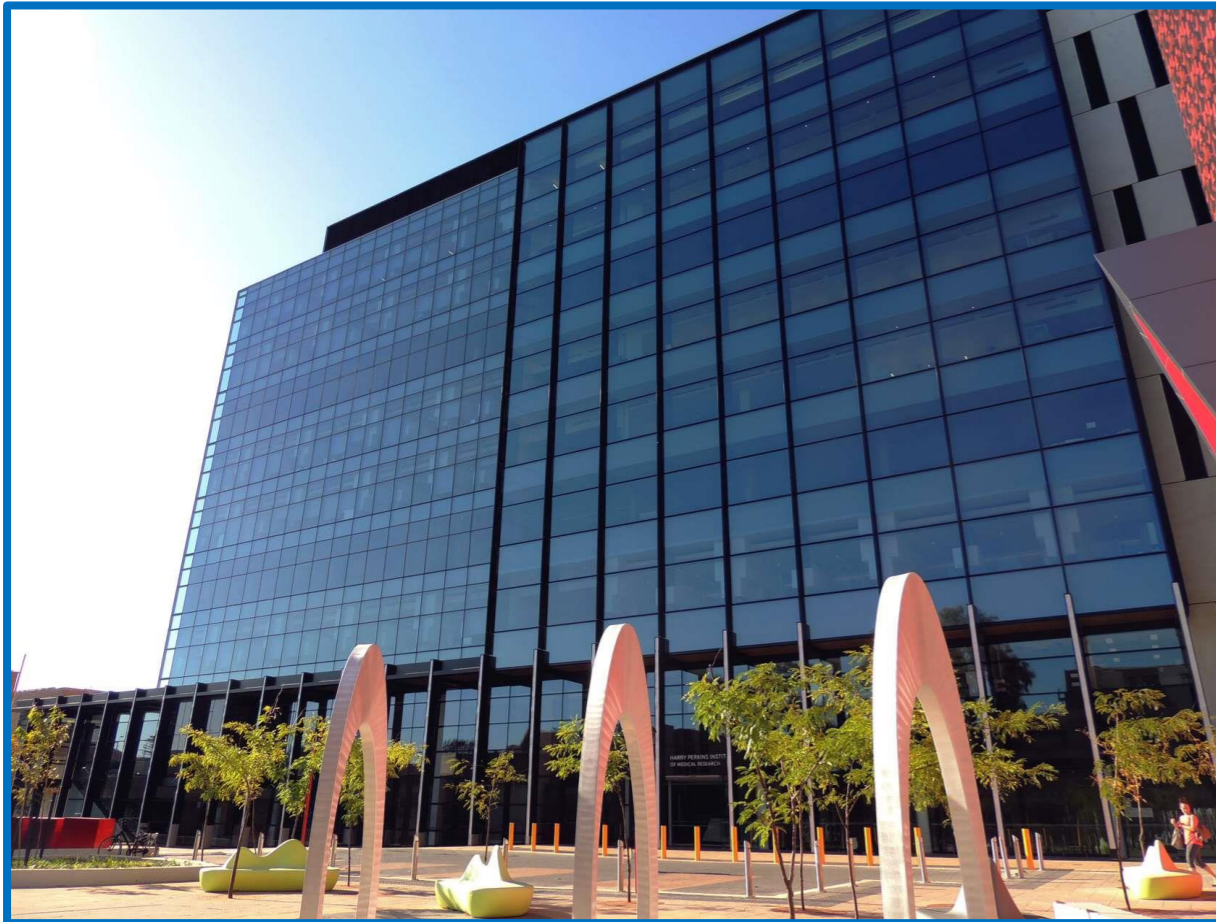
- **Develop a rapid diagnostic test for the identification of the SARS-CoV-2 virus**
  - Half of people tested positive for SARS-CoV-2 were reported as having no symptoms
  - Asymptomatic cases are the real and present risk of significant undetected community transmission of COVID-19
- **Develop a diagnostic test to determine why some people are more severely affected than others**
  - Involve isolating biomarkers that give insights into the progression of the COVID-19 disease
  - Predict which patients are at greatest risk of requiring significant medical intervention
  - Aim to improve triaging at hospitals when patients present with COVID-19

## OXIDATIVE STRESS (2-TAG)

- **The patented technology called "2-tag" measures the oxidative stress in a system (i.e. body of human or animal)**
- High levels of oxidative stress can be dangerous and have been linked to a wide range of chronic diseases including stroke, heart attack, Parkinson's disease, and muscular dystrophy and muscle damage
- Collaboration with the University of Western Australia to develop methodology that could become the next generation of medical diagnostic tests
- The 2-tag test demonstrated proof of concept with several publications targeting Duchenne muscular dystrophy
- **Global opportunity in human health, elite sport's health and animal health (e.g. Horse racing industry)**



## Proteomics International state-of-the-art biomarker analysis facilities



- World leading facility in Western Australia – Public Private Partnership co-investing >\$4m including from Federal and State Government agencies
- Best in class Quality Control testing
- Biosimilars & biologics - Assisting pharmaceutical companies develop generic drugs
- Food quality (e.g. milk)
- Pharmacokinetic (PK) testing for clinical trials
- World's first company to receive ISO 17025 Laboratory Accreditation for proteomics services (protein testing)
- **YoY Revenue growth**



# MILESTONES & UPCOMING CATALYSTS

## EXCEPTIONAL GLOBAL OPPORTUNITY

- ✓ **Proven diagnostics business with global potential**
- ✓ **Scalable licensing model with high margins and low rollout cost**
- ✓ **Minimal burn rate ensures rollout is funded**
  - Established revenue reduces burn, trending to cash flow positive
- ✓ **Strong IP position**
  - Patents granted in major jurisdictions for groundbreaking PromarkerD predictive test
- ✓ **Cutting-edge technology & proven platform - pipeline of potential globally significant tests**
  - Proof of concept established with PromarkerD: endometriosis and gastro undergoing pre-clinical work
- ✓ **World leading technology in an area of significant unmet medical need**

## SHARE PRICE CATALYSTS 2020-21

### PromarkerD

- **Results from Janssen studies – Stage 2**
  - diagnostic capability to assist drug developers to market kidney disease treatments
- **Further licencing deals in major territories**
  - diagnostics, pharmaceuticals, service providers
- Regulatory approvals – ISO 13485, FDA
- Reimbursement (Medicare) code in the USA
- Patents in other global jurisdictions

### Analytical services






- New contracts for protein QC, biosimilars & PK testing

### Diagnostic test development

- Endometriosis, gastro, COVID-19, asthma and lung disease
- Expansion into other chronic diseases & applications



# APPENDICES - PEER COMPARISON

	Stock Code	Company Focus	Market Capitalisation	Share Price	FY19 Revenue	FY19 Net Profit/Loss	Addressable Market(s) US\$Bn
 <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.	<b>£407m + US\$81m (~A\$852.5m)</b>	565p & US\$14.72	N/A	£6.9m (A\$12.6m) loss	US\$9.5Bn
 <b>Volpara Health Technologies</b>	VHT.ASX	SAAS Diagnostic technology that utilises AI to improve the early detection of breast cancer.	<b>A\$342m</b>	A\$1.37	NZ\$16.5m	NZ\$20.8m loss	US\$750m
 <b>Genetic Signatures</b>	GSS.ASX	Specialist molecular diagnostics (MDx) for the routine detection of infectious diseases. High volume and rapid tests. COVID-19 Focus	<b>A\$328m</b>	A\$2.30	A\$4.9m	A\$3.5m loss	US\$8.4Bn
 <b>Atomo Diagnostics</b>	AT1.ASX	Disposable rapid tests for COVID-19 and HIV.	<b>A\$224m</b>	A\$0.40	A\$0.54m	A\$5.9m loss	US\$4.57Bn
 <b>Proteomics International Laboratories</b>	PIQ.ASX	Predictive DKD blood test which identifies and measures panel of novel protein biomarkers. Simple, cost effective, mass market blood test.	<b>A\$55.6m</b>	A\$0.605	A\$1.5m	A\$2.1m loss	US\$5.4Bn

# BOARD & MANAGEMENT

DIRECTORS HOLD  
25%



**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.



**Richard Lipscombe** PhD (London), MA (Oxon), Founder & Managing Director

Successfully managed the Company since listing in April 2015. 30 years experience in research and development globally in academic and commercial entities. Technical expertise in chemistry, immunology, & biomarker discovery.



**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), recently serving 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.



**Chuck Morrison** BSc (Boston), MBA (Boston), Business Development

Over 35 years in life sciences, biotechnology, and diagnostic industries including DuPont and PerkinElmer.

# CONTACT



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