

ASX Release  
26 November 2020

ASX code: PIQ

# Proteomics International

LABORATORIES LTD

## AGM Investor Presentation

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) is pleased to release a copy of the AGM 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

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PIQ



# Proteomics International

LABORATORIES LTD

## AGM Presentation

26<sup>th</sup> November 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)
- Patented, cost-effective, easy to use technology
- Additional tests in the pipeline – Endometriosis, Gastro, Oxidative Stress, Oesophageal cancer, COVID-19, Asthma & Lung Disease

## BIOANALYTICAL SERVICES

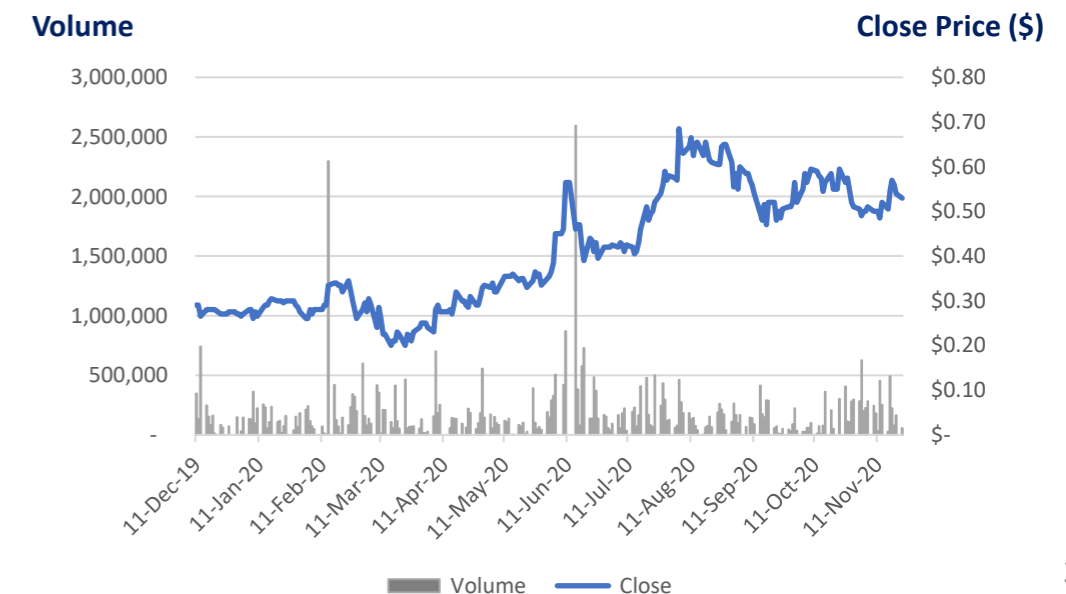
- Strong demand from industry for these specialised analytics
- Year on year revenue growth
- Enhanced capabilities with >\$4m invested in cutting-edge facility
- Revenue offsets the cash burn from R&D and product development

## FINANCIAL & CORPORATE

- Raised \$6m in heavily oversubscribed placement (October 2020)
- Implementing expansion strategies to accelerate growth

## CORPORATE SNAPSHOT – 23/11/2020

ASX code	PIQ
Share Price	\$0.53
Shares on issue (+ 5.6m options)	104.9m
Market Capitalisation	\$56m
Cash	\$8+m
Revenue & other income – FY20	\$3.0m
Directors Shareholding	22%



# Board & Management

DIRECTORS HOLD  
22%



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

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

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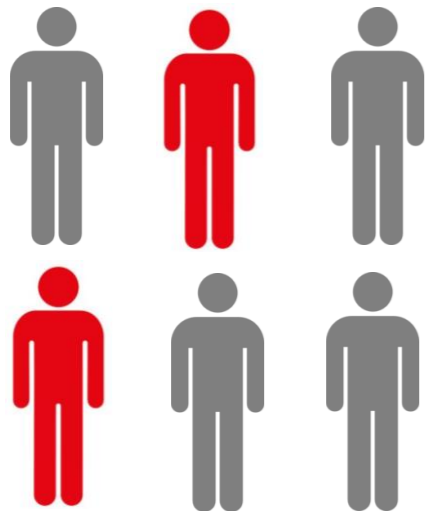
# Promarker – Platform Technology



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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 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 to bring the test to markets globally**

## **Enormous Market**



463m adults have diabetes globally - 1 in 3 currently have DKD

## **High Statistical Performance**



Peer reviewed publications - Analytical & Clinical validity evidence

## **Simple Technology Platform**

PromarkerD Immunoassay ready



Clinical pathology laboratories can easily introduce the PromarkerD immunoassay as an IVD kit or LDT

## **Regulatory Approval in Europe**



CE Mark registration received for the PromarkerD Immunoassay

## **Big Pharma Interested**



Collaboration with Janssen ongoing - global multi-centre clinical study

## **Therapeutic Treatments Available**



SGLT2 inhibitor class drugs used for type 2 diabetes recently approved as a new treatment of diabetic kidney disease

## **Reimbursement**

Engaged industry leading consultant to ensure payment coverage in the USA & obtain a unique US reimbursement code

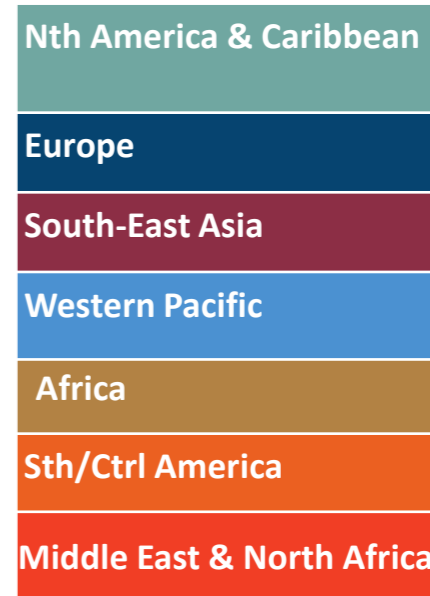
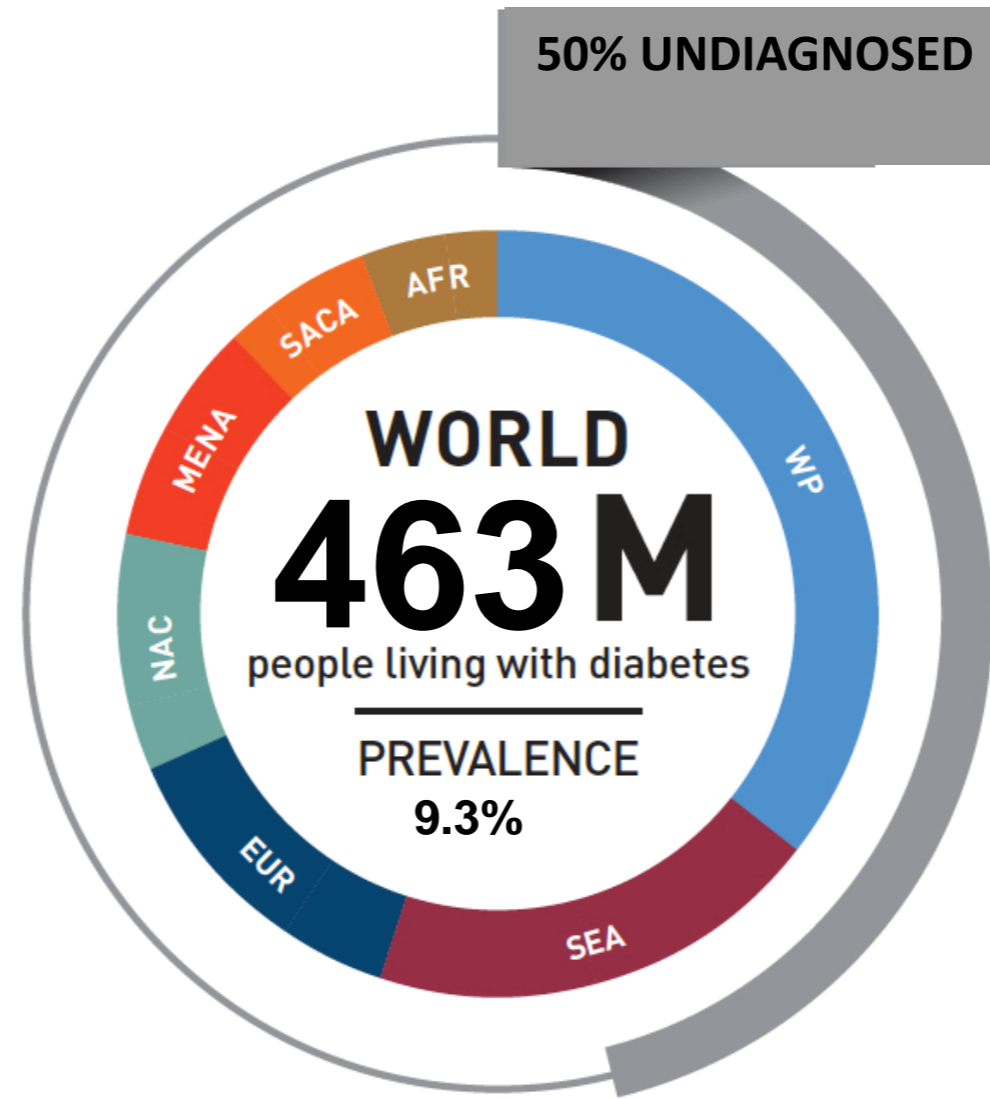
## **Regulatory Approvals Globally**

Engaging with partners and national regulators



# 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%
- Both markets driven by developments in personalized medicine and identification of biomarkers for disease diagnosis



2019

Targeting Type 2 Diabetes (~90% of diabetics)



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# PromarkerD - a Major Opportunity

## THE PROBLEM

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



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# PromarkerD Platforms

## 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

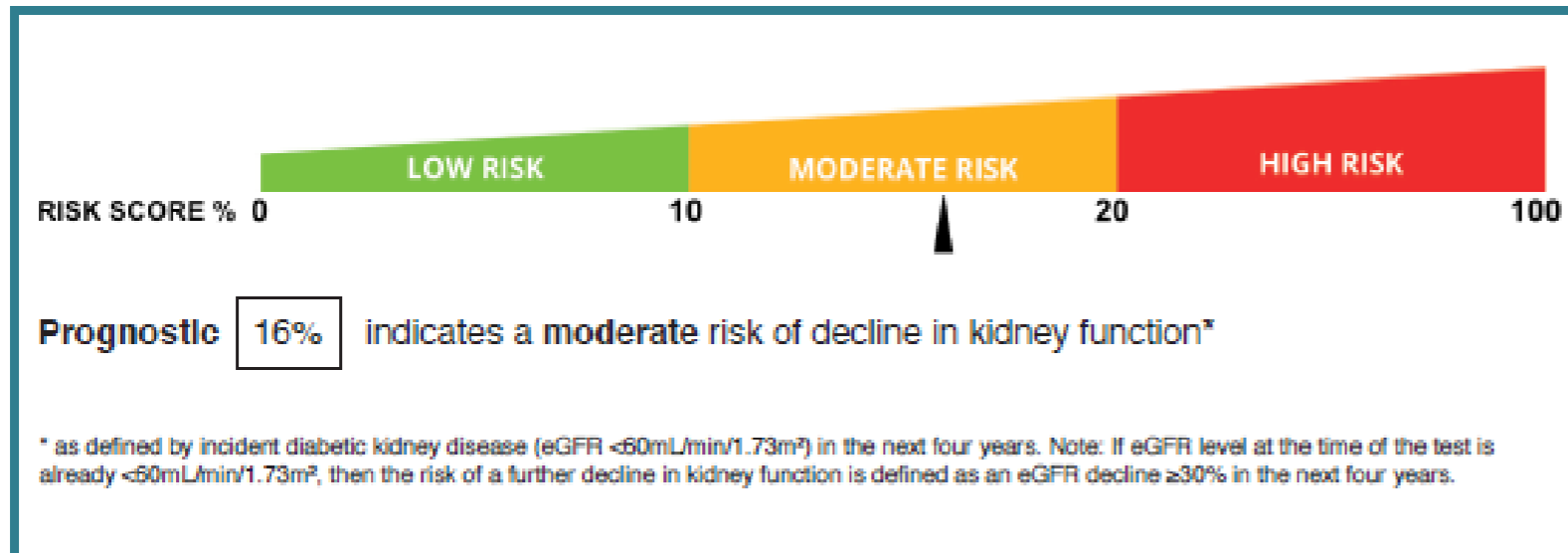
- **Cost-effective, easy-to-use** technology platforms
- **Regulatory approval** – European CE Mark registered (allows entrance into multiple markets globally)
- In commercial discussions with **pathology laboratories, diagnostics manufacturers, and pharmaceutical companies**

# PromarkerD in the Clinic



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## TEST RESULTS



## 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)

## 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

# PromarkerD - Janssen Collaboration



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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

### ➤ Global multi-centre study of over 3,000 people (at baseline)

- PromarkerD assessed for predicting disease outcomes in patients from the completed CANVAS clinical trial (CANagliflozin CardioVascular Assessment Study)

### ➤ PromarkerD independently validated for predicting DKD

- PromarkerD predicted DKD outcomes of the 4 year trial
- Patients predicted by PromarkerD to be at high-risk of DKD were 13.5 times more likely than the low-risk group to develop the disease, with the results showing high statistical significance ( $P = 1.3 \times 10^{-104}$ )
- Results co-presented at the 80<sup>th</sup> Scientific Sessions of the American Diabetes Association (June) & published in international journal (Oct)

### ➤ PromarkerD disease modelling ongoing

- Statistical analysis continuing to assess PromarkerD for predicting other kidney decline outcomes and cardiovascular disease (CVD)

## STAGE 2 STUDY

### ➤ Global multi-centre study of over 3,000 people (at trial end)

- Janssen elected to expand the collaboration in March 2020 and *further to extend the agreement until November 2021*
- Stage 2 study to determine if PromarkerD can help assess the effectiveness of canagliflozin as a treatment for DKD
- PromarkerD scores measured using the immunoassay test

### ➤ PromarkerD as a potential Complementary Diagnostic (CDx)

- The PromarkerD test could be used:
  - to capture at risk patients up to 4 years earlier
  - determine which patients are prescribed higher cost therapies
  - monitor a patient's response to treatment (potentially lifetime) and the ongoing risk of developing DKD

### ➤ PromarkerD vs drug treatment modelling ongoing

- Laboratory measurements completed & statistical analysis commenced: Results due early 2021

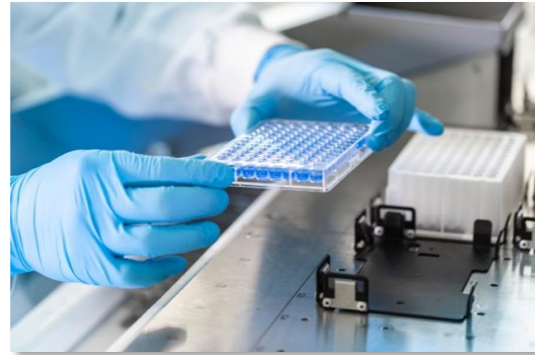


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# PromarkerD - Route To Market

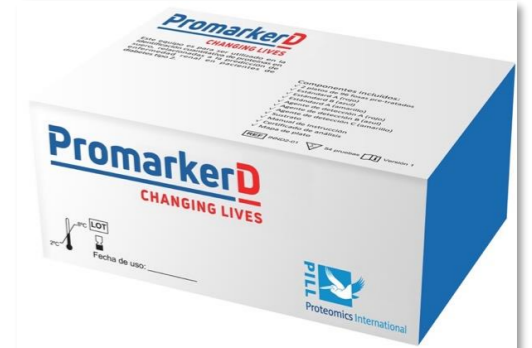
## LABORATORY DEVELOPED TEST (LDT)

- **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
- ***Roll-out commenced***



## 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

# PromarkerD - Market Opportunity



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## 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 in a market access study conducted by independent consultant].
- **Standard industry royalty rates range from 5-15%**

## Proteomics International patent portfolio and Market size

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	<i>Pending</i>	723,400
India	3012/DELNP/2013	<i>Pending</i>	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
<b>USA <sup>2,4</sup></b>	<b>US 9,146,243</b>	<b>Granted</b>	<b>30,987,900</b>
			<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).



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# PromarkerD - Recent Licence Agreements

## ITALY

- **First licence agreement for high throughput immunoassay – October 2020**
  - 3.7m people in Italy have type 2 diabetes (1 in 12)
  - Initial 2 year agreement with innovative Italian distributor Medical Horizons SRL
  - KOL's engaged to drive awareness and understanding of PromarkerD's benefits
  - *Test registered for use with Italian Ministry of Health*
  - *Sales expected early CY21*
  - Terms and pricing in line with company estimates

## ISRAEL

- **First licence agreement for high throughput immunoassay in the Middle East – November 2020**
  - 1.1m people in Israel have type 2 diabetes (1 in 8)
  - Israel is recognised as a global leader in the life-science industry and renowned for its early adoption of cutting-edge medical technologies.
  - Initial 2 year agreement with experienced and well known healthcare distributor, Zotal Ltd
  - KOL's being engaged to drive awareness and understanding of PromarkerD's benefits
  - Test is being registered with Israeli Department of Medical Devices at the Ministry of Health (~6 months)
  - Terms and pricing in line with company estimates

**Proteomics International is actively seeking to enter into further licence agreements across its primary target markets of Europe, the US and Asia**



# 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)



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# Diagnostics in Development: Endometriosis

## What Is Endometriosis?

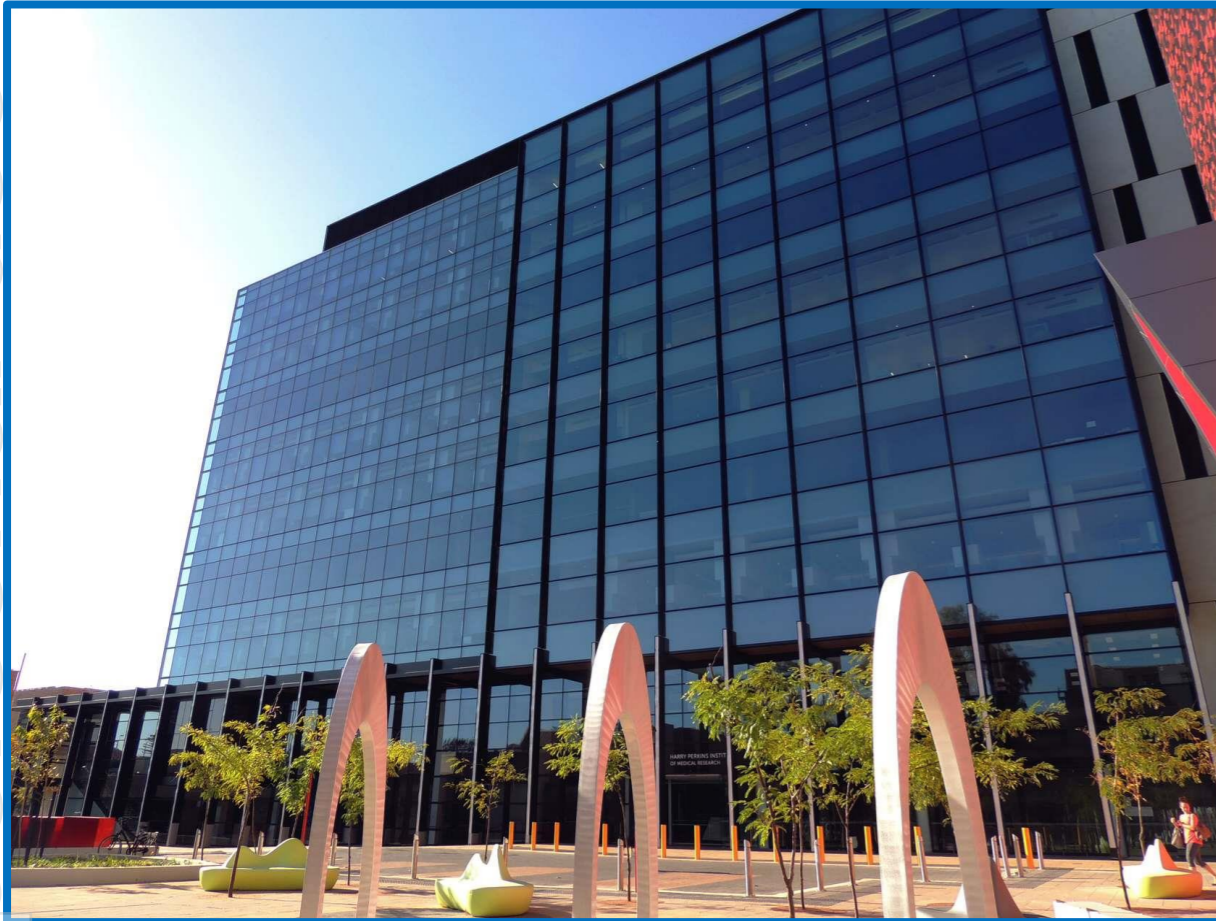
- ▶ A debilitating condition in which tissue that normally lines the uterus grows outside the uterus (on the ovaries, fallopian tubes or the intestines)
- ▶ The most common symptoms are chronic pain and menstrual irregularities
- ▶ Diagnosis typically takes 7 to 12 years due to the lack of a diagnostic 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
- ▶ *Proteomics is in advanced discussions to access a large cohort for its clinical validation study*



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



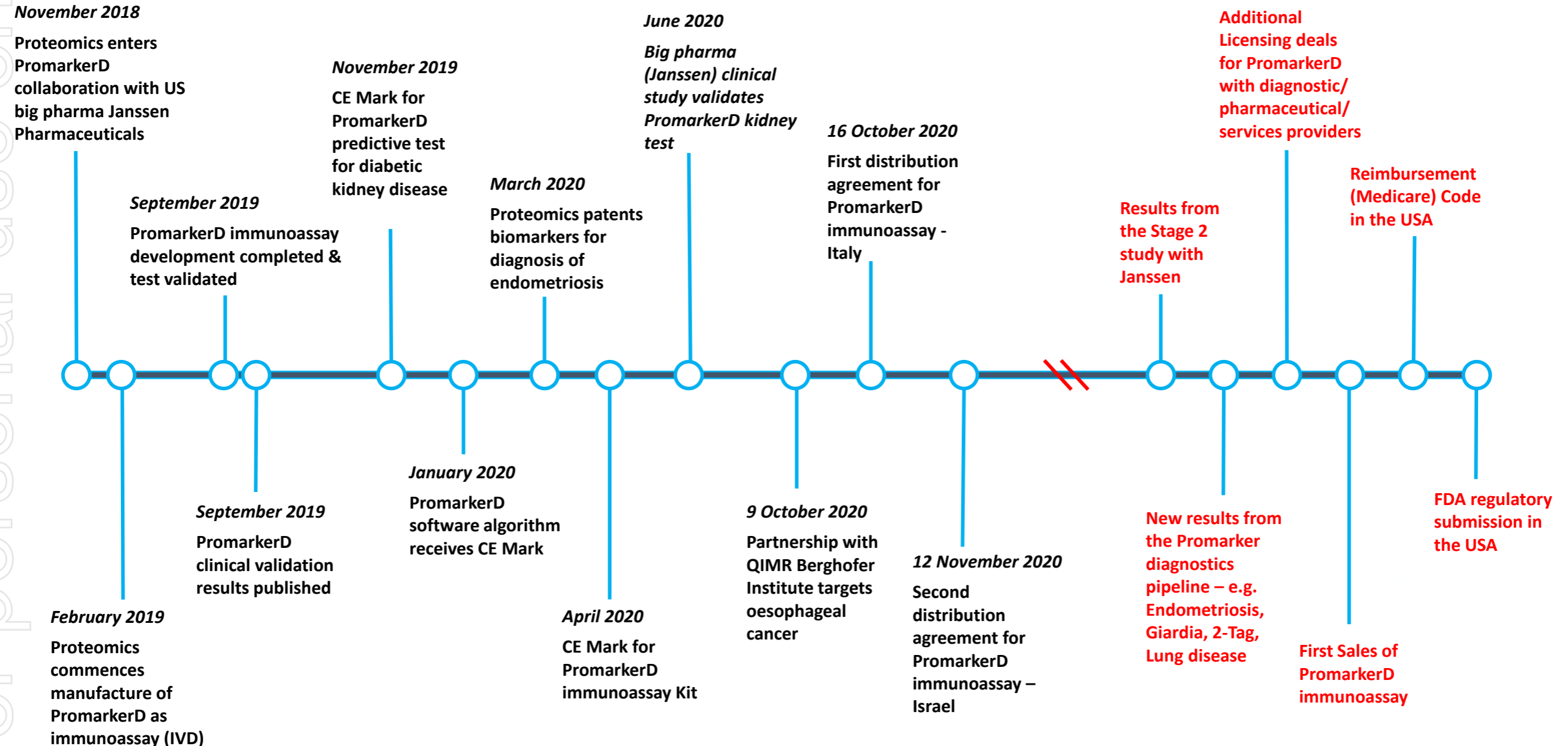
- World leading facility in Western Australia – Public Private Partnership co-invested >\$4m including from Federal and State Government agencies
- Best in class Quality Control testing
- Biosimilars & biologics - Assisting pharmaceutical companies develop generic drugs
- Food quality (e.g. milk)
- Pharmacokinetic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



# Promarker™ Timeline & Upcoming Milestones

## Two year targets and achievements

## Future targets





# PIQ: Value Inflection Points 2021

## 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

## ANTICIPATED SHARE PRICE CATALYSTS 2021

### PromarkerD

- Licencing deals in major territories: diagnostics, pharmaceuticals, or service providers
- Results from Janssen studies – Stage 2 (drug treatment) and Stage 1 (other disease prediction)
- First commercial sales of PromarkerD immunoassay
- Reimbursement (Medicare) code in the USA
- Regulatory approvals: ISO 13485 (manufacturing), international jurisdictions

### Analytical services

- Major contracts for QC testing, biosimilars, PK testing, or biomarker discovery

### Diagnostic test development

- Novel tests established for endometriosis, gastro infection (*Giardia*), oesophageal cancer, oxidative stress, lung disease

# Contact



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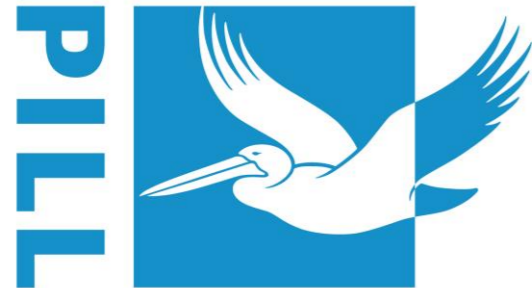
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# Appendices: Peer Comparison

Kudos only

	Stock Code	Company Focus	Market Capitalisation	Share Price	FY20 Revenue	FY20 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>£327m + US\$72m (~A\$692m)</b>	455p & US\$11.63	N/A	For FY19 £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\$335m</b>	A\$1.355	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\$250m</b>	A\$1.745	A\$11.3m	A\$2.0m loss	US\$8.4Bn
 <b>Atomo Diagnostics</b>	AT1.ASX	Disposable rapid tests for COVID-19 and HIV.	<b>A\$185m</b>	A\$0.33	A\$5.4m	A\$2.4m 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\$56m</b>	A\$0.53	A\$3.0m	A\$1.7m loss	US\$33.2Bn

# Appendices:

## Treatments for DKD - SGLT2 Inhibitors



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### 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-sgl2-ship>