ASX Release
26 November2020

ASX code: PIQ

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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Proteomics International
LABORATORIES LTD

AGM Presentation

26th November 2020

ASX: PIQ

BUILDING A GLOBAL
DIAGNOSTICS BUSINESS

Disclaimer

ASX:PIQ

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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

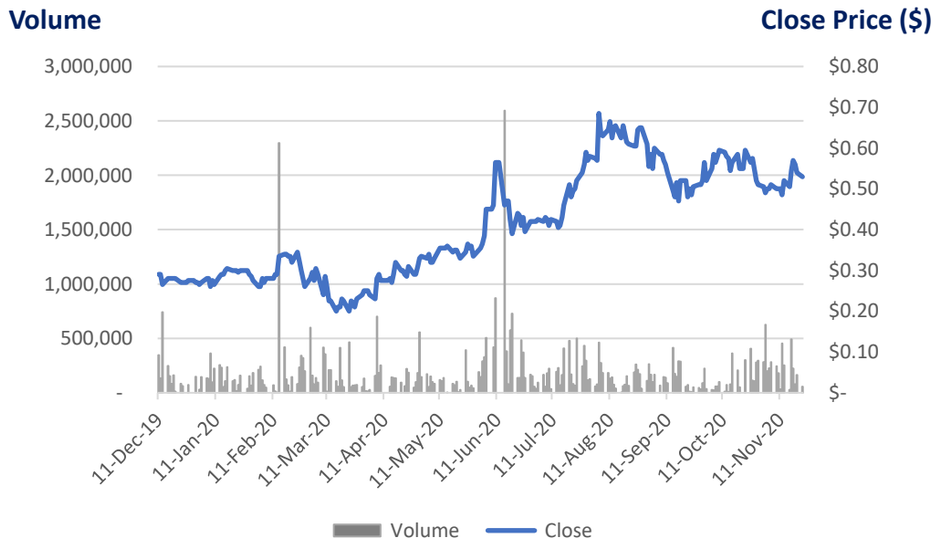
BIOANALYTICAL SERVICES

- 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.

Promarker – Platform Technology

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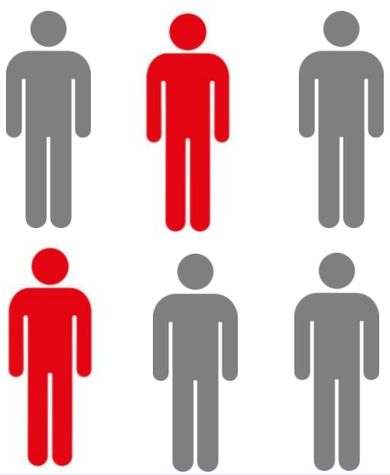
Promarker™ is a platform technology that can identify unique protein biomarkers ‘fingerprints’



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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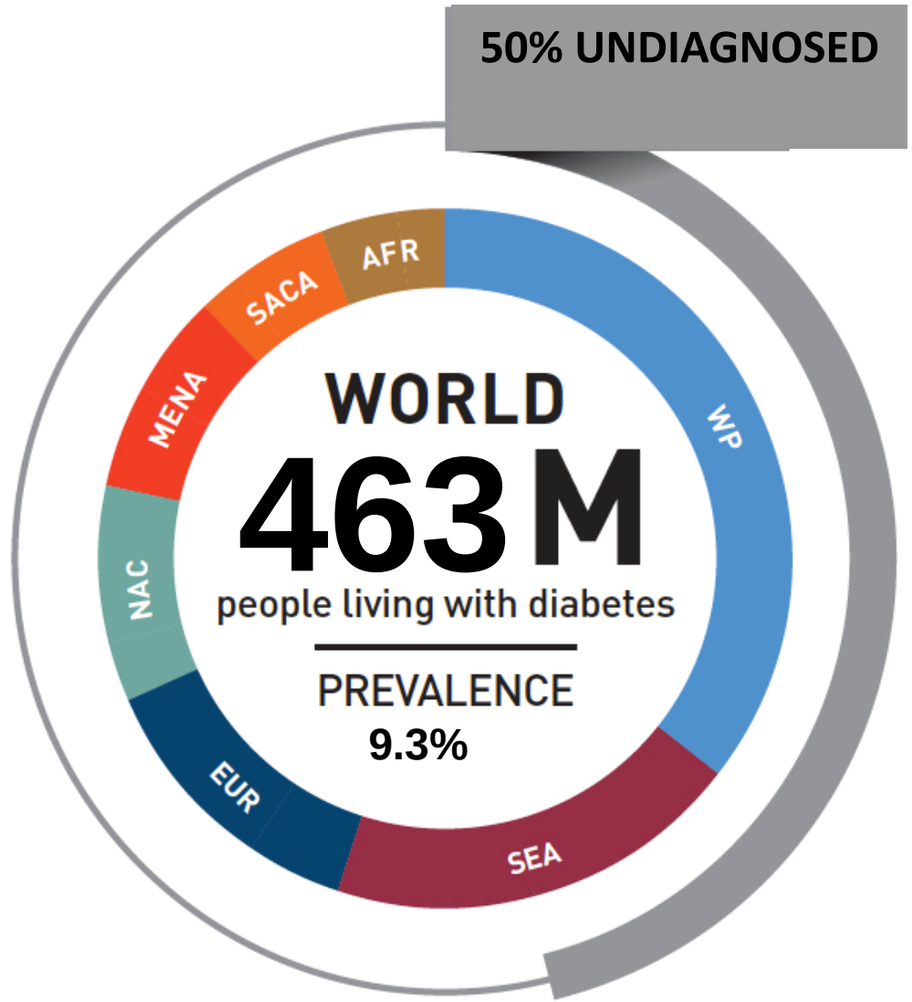
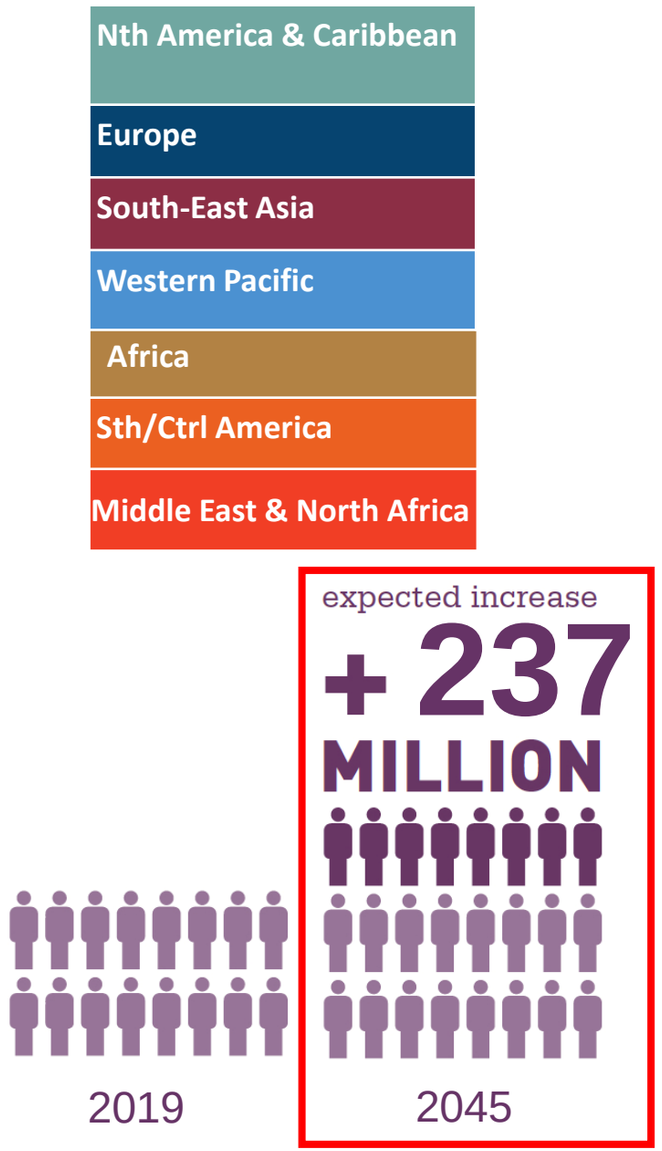
PromarkerD is <u>revenue ready</u> and Proteomics International is currently in discussions to bring the test to markets globally

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





Targeting Type 2 Diabetes (~90% of diabetics)

www.ncbi.nlm.nih.gov/books/NBK447315/
www.alliedmarketresearch.com/ivd-in-vitro-diagnostics-market
www.alliedmarketresearch.com/proteomics-market

International Diabetes Federation 2019

PromarkerD - a Major Opportunity

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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***

PromarkerD Platforms

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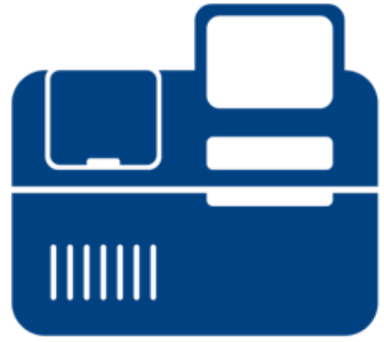
PREDICTIVE TEST for DIABETIC KIDNEY DISEASE

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 (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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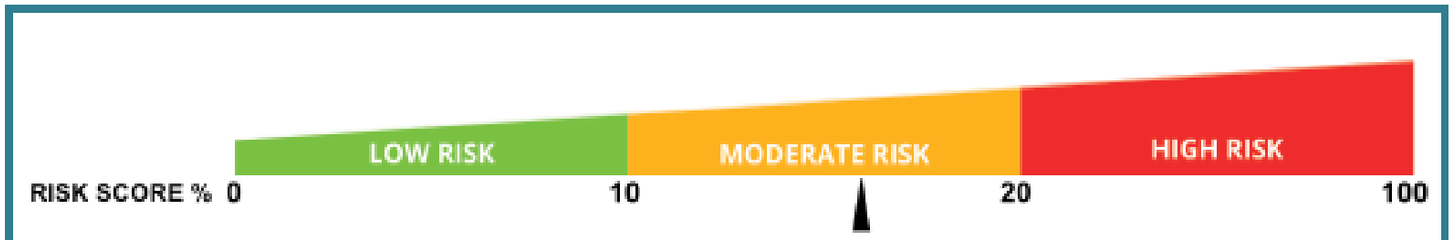
TEST RESULTS



Prognostic 16% indicates a **moderate** risk of decline in kidney function*

* 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.

Result Interpretation

Low Risk	Standard diabetes management; Status tested annually.
Moderate Risk	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.
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. 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 = $1.3x10^{-104}$)
- Results co-presented at the 80th 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

PromarkerD - Route To Market

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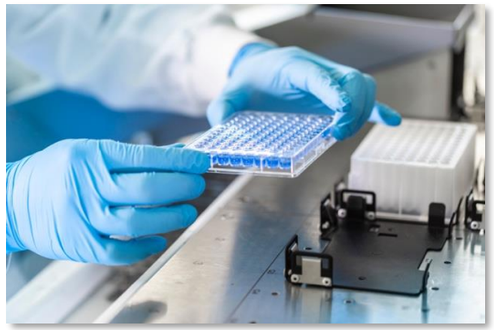
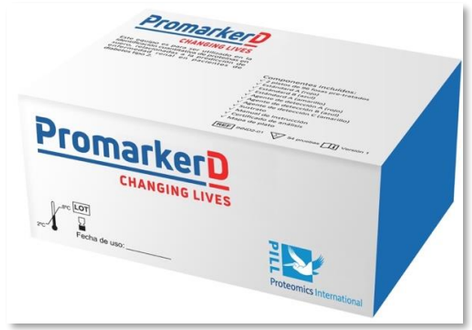
LABORATORY DEVELOPED TEST (LDT)

- **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 [1]
Australia [2]	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 [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 29.6 million 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).

PromarkerD - Recent Licence Agreements

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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

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)

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

Diagnostics in Development: 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
- *Proteomics is in advanced discussions to access a large cohort for its clinical validation study*

Analytical Services

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

November 2018

Proteomics enters PromarkerD collaboration with US big pharma Janssen Pharmaceuticals

February 2019

Proteomics commences manufacture of PromarkerD as immunoassay (IVD)

September 2019

PromarkerD immunoassay development completed & test validated

September 2019

PromarkerD clinical validation results published

November 2019

CE Mark for PromarkerD predictive test for diabetic kidney disease

January 2020

PromarkerD software algorithm receives CE Mark

March 2020

Proteomics patents biomarkers for diagnosis of endometriosis

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 November 2020

Second distribution agreement for PromarkerD immunoassay – Israel

Future targets

Results from the Stage 2 study with Janssen

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

Additional Licensing deals for PromarkerD with diagnostic/ pharmaceutical/ services providers

First Sales of PromarkerD immunoassay

Reimbursement (Medicare) Code in the USA

FDA regulatory submission in the USA

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

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Proteomics International LABORATORIES LTD

Appendices: Peer Comparison

	Stock Code	Company Focus	Market Capitalisation	Share Price	FY20 Revenue	FY20 Net Profit/Loss	Addressable Market(s) US$Bn
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.	**£327m + US$72m (~A$692m)**	455p & US$11.63	N/A	For FY19 £6.9m (A$12.6m) loss	US$9.5Bn
Volpara Health Technologies	VHT.ASX	SAAS Diagnostic technology that utilises AI to improve the early detection of breast cancer.	**A$335m**	A$1.355	NZ$16.5m	NZ$20.8m loss	US$750m
Genetic Signatures	GSS.ASX	Specialist molecular diagnostics (MDx) for the routine detection of infectious diseases. High volume and rapid tests. COVID-19 Focus	**A$250m**	A$1.745	A$11.3m	A$2.0m loss	US$8.4Bn
Atomo Diagnostics	AT1.ASX	Disposable rapid tests for COVID-19 and HIV.	**A$185m**	A$0.33	A$5.4m	A$2.4m loss	US$4.57Bn
Proteomics International Laboratories	PIQ.ASX	Predictive DKD blood test which identifies and measures panel of novel protein biomarkers. Simple, cost effective, mass market blood test.	**A$56m**	A$0.53	A$3.0m	A$1.7m loss	US$33.2Bn

Source: Bloomberg, company filings. Market data as at 23 Nov 2020, exchange rates of AUDGBP 0.55 and AUDUSD 0.73

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-boehringers-jardiance-in-chronic-kidney-disease/*
**https://www.fiercepharma.com/pharma/invokana-win-kidney-patients-could-help-j-j-right-sglt2-ship*