



**Proteomics International**

LABORATORIES LTD

**ASX Release**

**5 June 2020**

**ASX code: PIQ**

## **Investor Presentation**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), a pioneer in predictive diagnostics, is pleased to release a copy of its latest Investor Presentation which provides further details on the PromarkerD predictive test for diabetic kidney disease and additional tests in the company's pipeline. This presentation is being provided as a virtual investor roadshow.

Authorised by Dr Richard Lipscombe (Managing Director) on behalf of the Board of PIQ.

ENDS

**About Proteomics International Laboratories (PILL) ([www.proteomicsinternational.com](http://www.proteomicsinternational.com))**

Proteomics International (Perth, Western Australia) is a wholly owned subsidiary and trading name of PILL (ASX: PIQ), a medical technology Company at the forefront of predictive diagnostics and bio-analytical services. The Company specialises in the area of proteomics – the industrial scale study of the structure and function of proteins. It received the world's first ISO 17025 laboratory accreditation for proteomics services, and operates from state-of-the-art facilities located on Perth's QEII Medical Campus.

Proteomics International's business model is centred on the commercialisation of the Company's high-speed, low cost predictive test for diabetic kidney disease, PromarkerD. The Company offsets the cash burn from R&D and product development through provision of specialist analytical services, whilst using its proprietary Promarker™ technology platform to create a pipeline of novel diagnostic tests.

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PIQ



# Proteomics International

LABORATORIES LTD

## Investor Presentation

5<sup>th</sup> June 2020

ASX: PIQ

BUILDING A GLOBAL  
DIAGNOSTICS BUSINESS

# DISCLAIMER



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You should not rely upon anything in this presentation and/or any information obtained from the Company, its Directors or their associates in deciding whether or not to seek to purchase the shares of the Company. This is not an offer to subscribe for securities in the Company.

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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**

## PREDICTIVE DIAGNOSTICS

### PromarkerD

- World's first predictive diagnostic test for diabetic kidney disease
- Accurately predicts four years prior to typical diagnosis
- Predictive diagnosis can delay disease onset, resulting in significant benefits to the patient and healthcare system
- 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 – 04/6/2020

ASX code	PIQ
Share Price	\$0.385
Shares on issue (+ ~3m options)	92m
Market Capitalisation	\$35.4m
Enterprise Value	\$32.3m
Cash	\$3.1m
Cash Runway	> 12 months
Revenue & other income – FY19	\$2.7m
Directors Shareholding	25%



# BUILDING A GLOBAL DIAGNOSTICS BUSINESS



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<b>ENORMOUS MARKET</b>	PromarkerD, a predictive test for diabetic kidney disease (DKD) is being rolled out now. 463m adults have diabetes globally – 1 in 3 currently have DKD.
<b>DE-RISKED CLINICALLY</b>	PromarkerD clinical studies completed and validated by peer reviewed publications.
<b>COMMERCIALY READY</b>	Licensing deals for PromarkerD have been executed in Mexico, Spain & Dominican Republic. In discussions with potential global partners. Test launched in Europe and DR.
<b>GLOBAL SCALABILITY</b>	PromarkerD is being rolled out through established diagnostic laboratories under license/royalty agreements.
<b>JANSSEN COLLABORATION</b>	PromarkerD utilised to help assess the effectiveness of canagliflozin (Janssen drug) as a treatment for DKD. Large opportunity if PromarkerD becomes a Complementary Diagnostic.
<b>LIMITED COMPETITION</b>	PromarkerD is the world's first commercial test for predicting the onset of diabetic kidney disease. Patented globally.
<b>DEEP PIPELINE</b>	PromarkerD is the first commercial application of the Company's Promarker™ platform technology. The technology is also being applied to Endometriosis, COVID-19, Gastro, Oxidative Stress, Asthma & Lung Disease - all major market opportunities.
<b>LEAN AND SCALABLE</b>	Low fixed costs, strong balance sheet and already generating income over A\$2.7m (FY19). Additional major territories under discussion. Truly a global opportunity.
<b>ALIGNED MANAGEMENT</b>	Highly credentialed and experienced Board and Management that are aligned with shareholders. Founder & MD, Dr Richard Lipscombe holds 20.7% - Directors hold total ~25%.

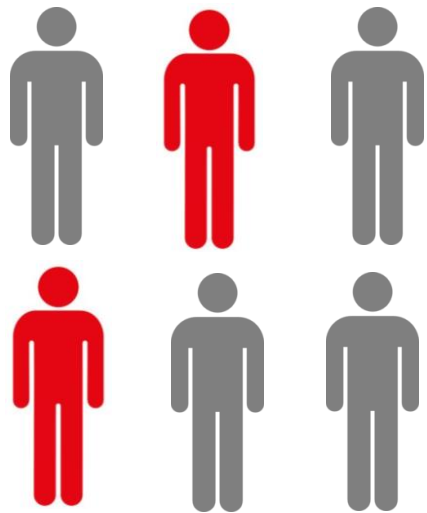


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# PROMARKER – PLATFORM TECHNOLOGY



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



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# PromarkerD PLATFORM & ANALYTICAL SERVICES

## PromarkerD – DIABETIC KIDNEY DISEASE TEST

PromarkerD assay can be readily ported to different platforms



Immunoassay Kit



LDT



Automated Immunoassay

- Licensing deals executed in Mexico, Dominican Republic, Spain
- **Janssen Pharmaceuticals (J&J) Collaboration**
- Test launched and sales commencing
- Pipeline tests: **Endometriosis, COVID-19, Oxidative Stress, Asthma & lung disease** - all major global opportunities

## ANALYTICAL SERVICES

State-of-the-art biomarker analysis facility



- World leading facility in Western Australia - \$4m co-investment from Federal and State Government agencies
- Best in class Quality Control testing
- Biosimilars & biologics
- Food quality (e.g. milk)
- Pharmacokinetic (PK) testing for clinical trials
- **YoY Revenue growth**



# PromarkerD

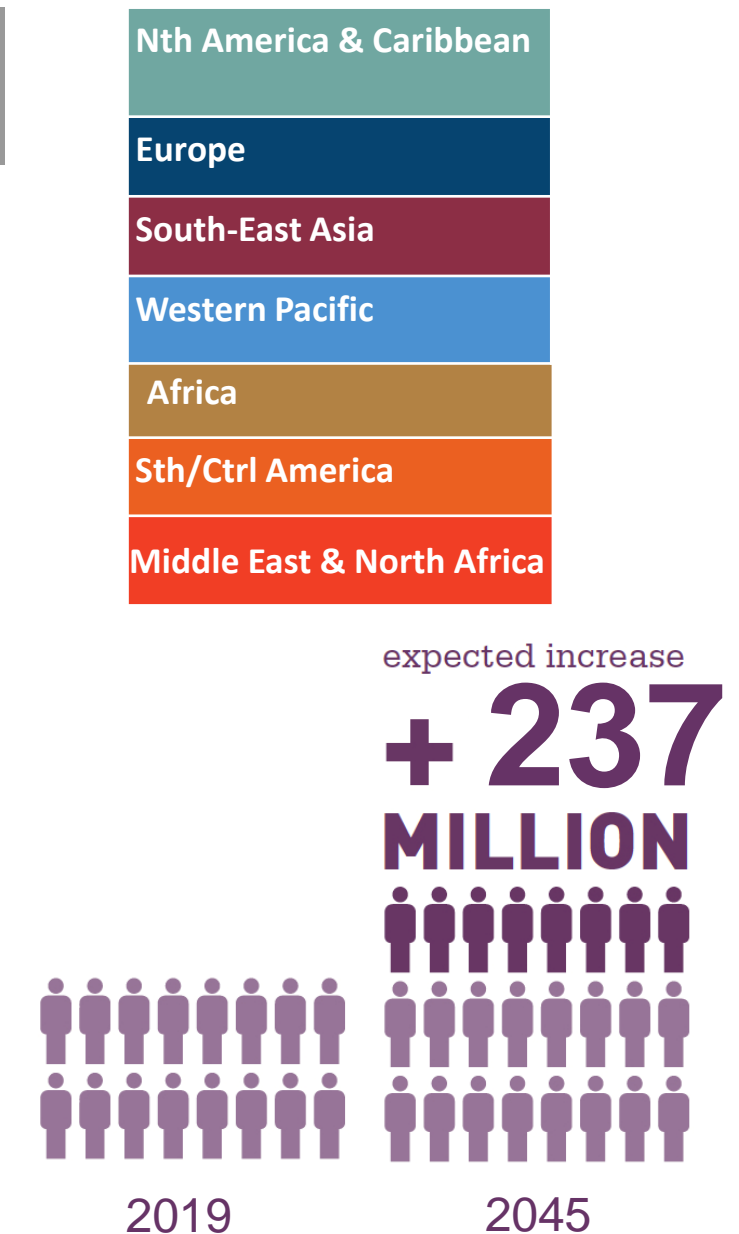


**PREDICTIVE TEST FOR DIABETIC KIDNEY DISEASE**



# MARKET SIZE?

- Hundreds of millions of people could benefit from the PromarkerD test via early treatment to mitigate the onset of kidney disease. Kidney disease is one of the major complications of diabetes and is fatal unless managed by dialysis which is costly and detrimental to quality of life.
- Globally, kidney disease and the diabetes epidemic cost health systems over \$850 billion annually.



International Diabetes Federation 2019



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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.**
  - ▶ There is currently no available mass-market, affordable test for predicting the onset of diabetic kidney disease
  - ▶ Diabetic kidney disease **leads to 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 diagnostic test for diabetic kidney disease

- ▶ PromarkerD can **diagnose** diabetic patients already suffering from chronic kidney disease that the current gold standard tests miss
- ▶ PromarkerD can predict the onset of disease **before** clinical symptoms appear
- ▶ **Doctors can then prescribe an early therapeutic treatment to stop the onset of disease**

# MAJOR COST/BENEFIT FACTOR TO DRIVE UPTAKE



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With PromarkerD		Without PromarkerD
Unequivocal Cost Benefit		
Test Price <b>US\$55</b> Predicts kidney disease with 86% accuracy up to four years out	VS	Dialysis cost <b>US\$72,000</b> per year ongoing for the patient's life
Unequivocal Patient Benefit		
Non invasive blood test Patients can alter habits / receive treatment to stop onset of the disease	VS	<b>Dialysis machine for term of life</b>

# JANSSEN COLLABORATION



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Proteomics 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

- To assess PromarkerD predictive DKD capabilities in a large and diverse patient cohort to Big Pharma standards
- Results of the first phase to be co-presented with Janssen at the world's leading diabetes conference, the 80<sup>th</sup> Scientific Sessions of the American Diabetes Association (ADA) on 13<sup>th</sup> June 2020
- **If successful, it will be independent, Big Pharma validation of PromarkerD - this will be significant for the commercialisation and promotion of PromarkerD in the US and globally**

## 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 expected to report later in CY2020
- **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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# JANSSEN COLLABORATION

## CANAGLIFLOZIN (INVOKANA™)

- Canagliflozin has been sold as a diabetes treatment, for blood glucose control since 2013
- In 2019 Janssen's Phase 3 'CREDESCENCE' clinical trial found that canagliflozin significantly reduces the risk of renal failure in patients with type 2 diabetes and chronic kidney disease
- First drug in 20 years to significantly reduce the risk of renal failure, dialysis or kidney transplantation
- Invokana™ revenue fell to US\$881 million in 2018 from US\$1.4 billion in 2016\* - opportunity for Janssen to turn this around with PromarkerD



## COMMERCIAL UPSIDE

- PromarkerD could become a powerful tool for pharmaceutical companies that are:
  - commercialising/promoting an approved treatment - a CDx test will guide a patient to their treatment
  - conducting clinical trials - patient populations can be targeted/recruited to enhance overall efficacy (reduce placebo or negative response)
- Potential to capture a patient group up to four 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://www.fiercepharma.com/pharma/invokana-win-kidney-patients-could-help-j-j-right-sglt2-ship>

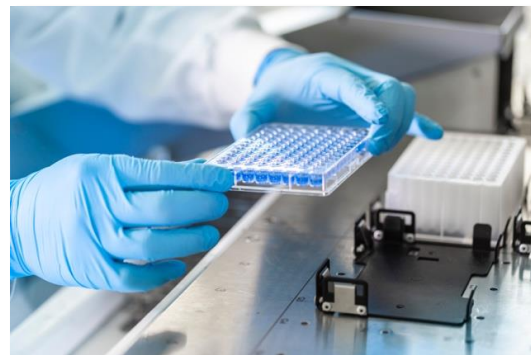
# ROUTE TO MARKET



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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**

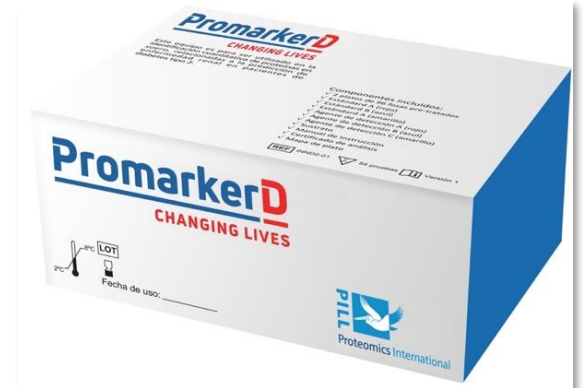


### Example – LDT with Atturos

- Clinical diagnostics firm, Atturos (Ireland), is equipped to run the mass spectrometry LDT version of PromarkerD, making the test available for license partners in the European Market

## 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**



### Immunoassay production







- TGR Biosciences (Australia) developed the PromarkerD advanced immunoassay for use across global markets
  - kit version is subject to regulatory approval in the US (FDA)





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# MARKET BREAKDOWN – PromarkerD

REGION		PARTNER	MARKET SIZE (DIABETICS)	ADDRESSABLE MARKET P.A.	TOTAL POTENTIAL OPPORTUNITY*
	Spain	Patia Europe	3.6m	US\$200m	US\$20m p.a.
	Mexico	Patia Biopharma	13m	US\$720m	US\$72m p.a.
	Dominican Republic	Omics Global	1.1m	US\$60m	US\$6m p.a.
TARGET MARKETS					
	United States	In Discussions	30m	US\$1.65Bn	US\$165m p.a.
	European Union	In Discussions	58m	US\$3.2Bn	US\$319m p.a.
	Japan	In Discussions	10m	US\$550m	US\$55m p.a.
		Total	98m	US\$5.4Bn	US\$539m p.a.

\* Assumption: Total \$ Market opportunity p.a. for PIQ using Test Price US\$55 & Royalty 10%

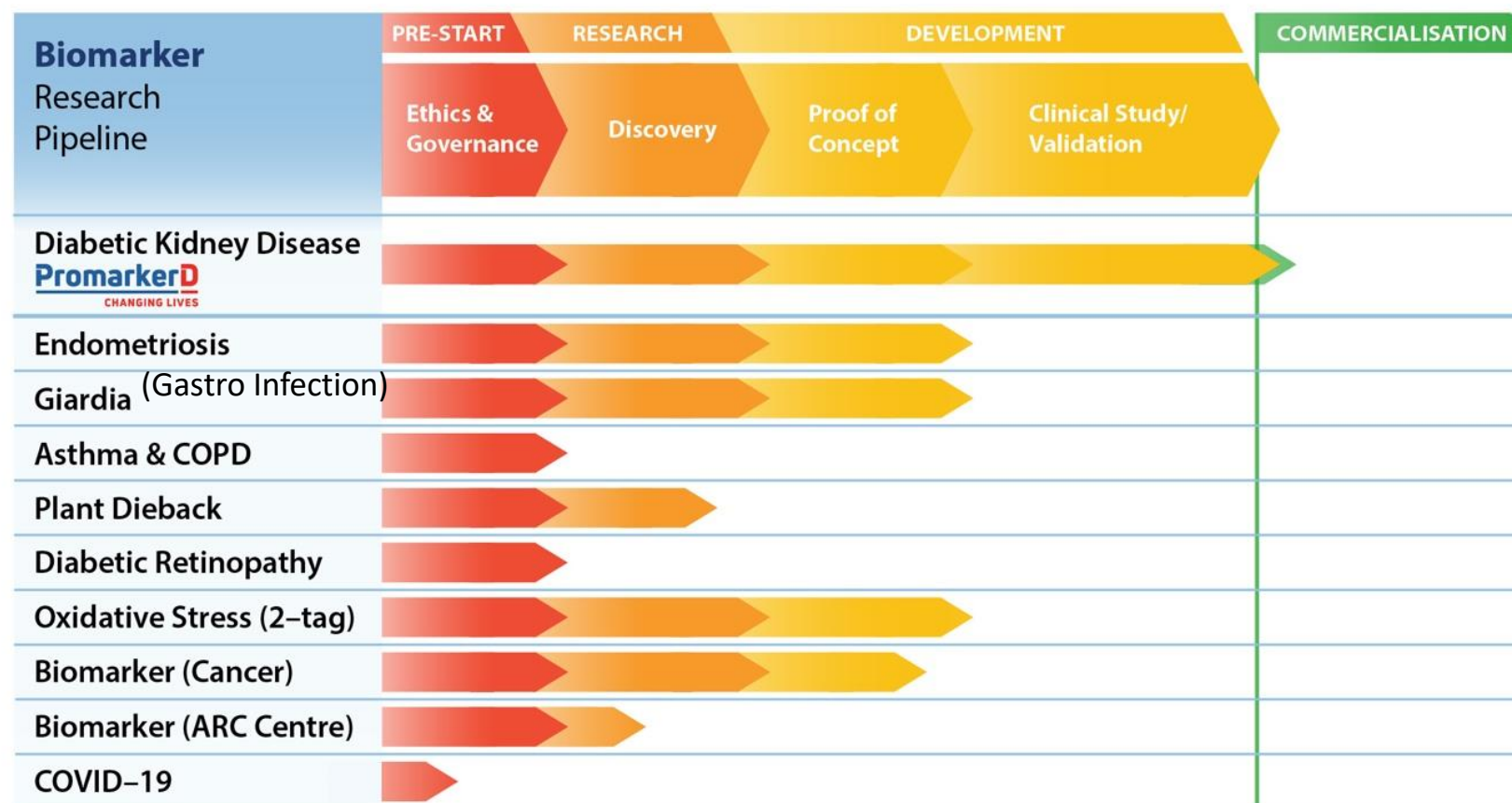


# DIAGNOSTICS PIPELINE

## 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
- ▶ Affects 1 in 9 women and costs Australia over AU\$10 billion a year
- ▶ 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



# 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)**

# ANALYTICAL SERVICES



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**WORLD'S FIRST COMPANY TO RECEIVE ISO 17025 LABORATORY ACCREDITATION  
FOR PROTEOMICS SERVICES (PROTEIN TESTING)**

## **BIOSIMILARS & BIOLOGICS**

**Assisting pharmaceutical companies  
develop generic drugs**

## **PHARMACOKINETIC TESTING**

**Pre-clinical and clinical quantitative  
testing of any new investigational drug**

**PROTEOMICS' ANALYTICAL SERVICES HAVE DELIVERED YoY REVENUE GROWTH  
OFFSETTING R&D AND PRODUCT DEVELOPMENT COSTS**

**RECENT UPGRADE OF FACILITY VIA \$4M CO-INVESTMENT FROM FEDERAL AND STATE  
GOVT CONFIRMS PROTEOMICS INTERNATIONAL AS A LEADER IN ITS FIELD**



# MILESTONES & UPCOMING CATALYSTS

## EXCEPTIONAL GLOBAL OPPORTUNITY

- ✓ **Proven diagnostics business with global potential**
- ✓ **Scalable licensing model with high margins and negligible 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 ground-breaking PromarkerD diagnostic algorithm
- ✓ **Cutting-edge technology & proven platform - pipeline of potential globally significant tests**
  - Proof of concept established with PromarkerD: endometriosis, COVID-19 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 1 & 2**
  - diagnostic capability to assist drug developers to market kidney disease treatments
- **Further licencing deals in major territories**
  - diagnostics, pharmaceuticals, service providers
- Regulatory approvals – FDA
- Reimbursement (Medicare) code in the USA
- Patents in other global jurisdiction

### Analytical services

- New contracts for protein QC, biosimilars & PK testing






### Diagnostic test development

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



# APPENDICES - PEER COMPARISON

**Proteomics is significantly undervalued vs ASX and International diagnostic peers**

	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	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>£248m (A\$450m)</b>	417p	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\$346m</b>	A1.405	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\$332m</b>	A\$2.26	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\$127m</b>	A\$0.315	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 (\$55 per test), mass market blood test.	<b>A\$35.5m</b>	A\$0.385	A\$1.5m	A\$2.1m loss	US\$5.4Bn





# PROTEOMICS Vs TYPICAL BIOTECHS

**ALL THE UPSIDE WITHOUT THE CLINICAL RISKS, COSTS & EXTENDED TIMELINES**

Features	PIQ	Typical Biotechs
Enormous markets	✓	✓
Minimal clinical risk	✓	X
No waiting for results	✓	X
Short clinical development (for new products)	✓	X
No binary outcome	✓	X
Licensing deals executed	✓	X
Commercially ready product(s) – revenue generating	✓	X
Existing revenues and low cash burn	✓	X
Limited capital requirements	✓	X
Platform technology	✓	Potentially
Peer reviewed	✓	Potentially
Tight capital structure	✓	Potentially



# 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, incoming 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



ASX:PIQ

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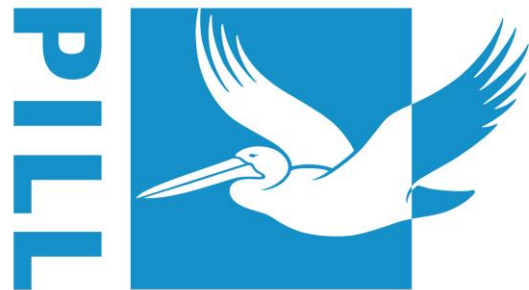
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