



Proteomics International

LABORATORIES LTD

**ASX Release
9 March 2021**

ASX code: PIQ

Investor Presentation

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) is pleased to release a copy of the presentation to be provided by Dr Richard Lipscombe to delegates at the Euroz Hartleys Institutional Conference to be held on Rottnest Island, Western Australia today.

Authorised by the Board of Proteomics International Laboratories Ltd (ASX:PIQ).

ENDS

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Proteomics International
LABORATORIES LTD

Investor Presentation

Euroz Hartleys Rottnest Island Institutional Conference

9-11 March 2021

**BUILDING A GLOBAL
DIAGNOSTICS BUSINESS**

ASX: PIQ



Disclaimer



ASX:PIQ

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Corporate Overview



ASX:PIQ

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, 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 – 05/03/2021

ASX code	PIQ
Share Price	A\$1.12
Shares on issue (+ 7.7m options)	105m
Market Capitalisation	A\$118m
Cash	A\$7.5m
Revenue & other income – FY20	A\$3.0m
Net cash burn – FY20	A\$1.6m
Directors Shareholding	22%



Board & Management



ASX:PIQ



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

Led the Company from foundation through listing in 2015 to today. 30 years biotechnology experience in R&D and product commercialisation in academic and commercial entities. Technical expertise in chemistry, immunology, biomarker discovery & clinical proteomics.



Roger Moore R (Denmark), BPharm (U.Syd), Non-Executive Director

International pharmaceutical industry experience spanning 40 years, including almost 30 years as President of Novo Nordisk Japan. From 2000, he was appointed Novo Nordisk's Senior Vice President, Japan & Oceania Region. He has also served as a member of the Senior Management Board, Novo Nordisk A/S.



Paul House GAICD, BCommerce (UWA), Non-Executive Director

Over 25 years with multi-national corporations, CEO of Imdex (ASX:IMD), 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.

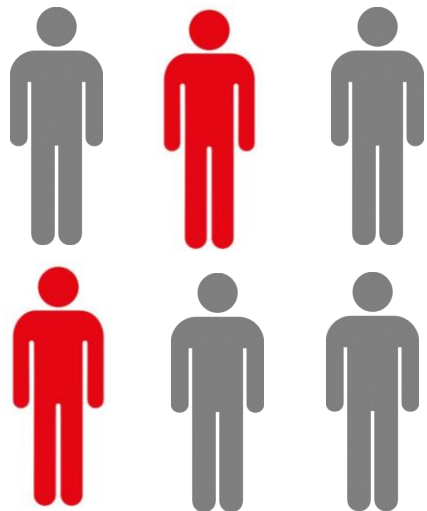


ASX:PIQ

Promarker – Platform Technology



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



The platform identifies and links the unique protein biomarkers to specific diseases, enabling Proteomics International to create novel diagnostic tests



PREDICTIVE TEST FOR DIABETIC KIDNEY DISEASE

THE PROBLEM

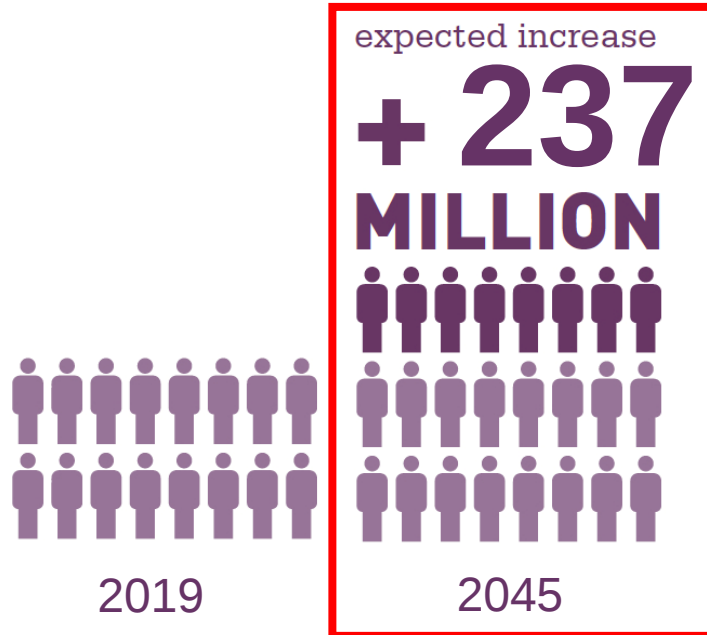
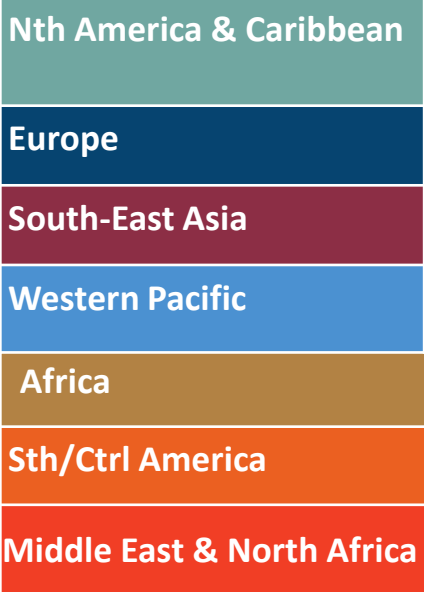
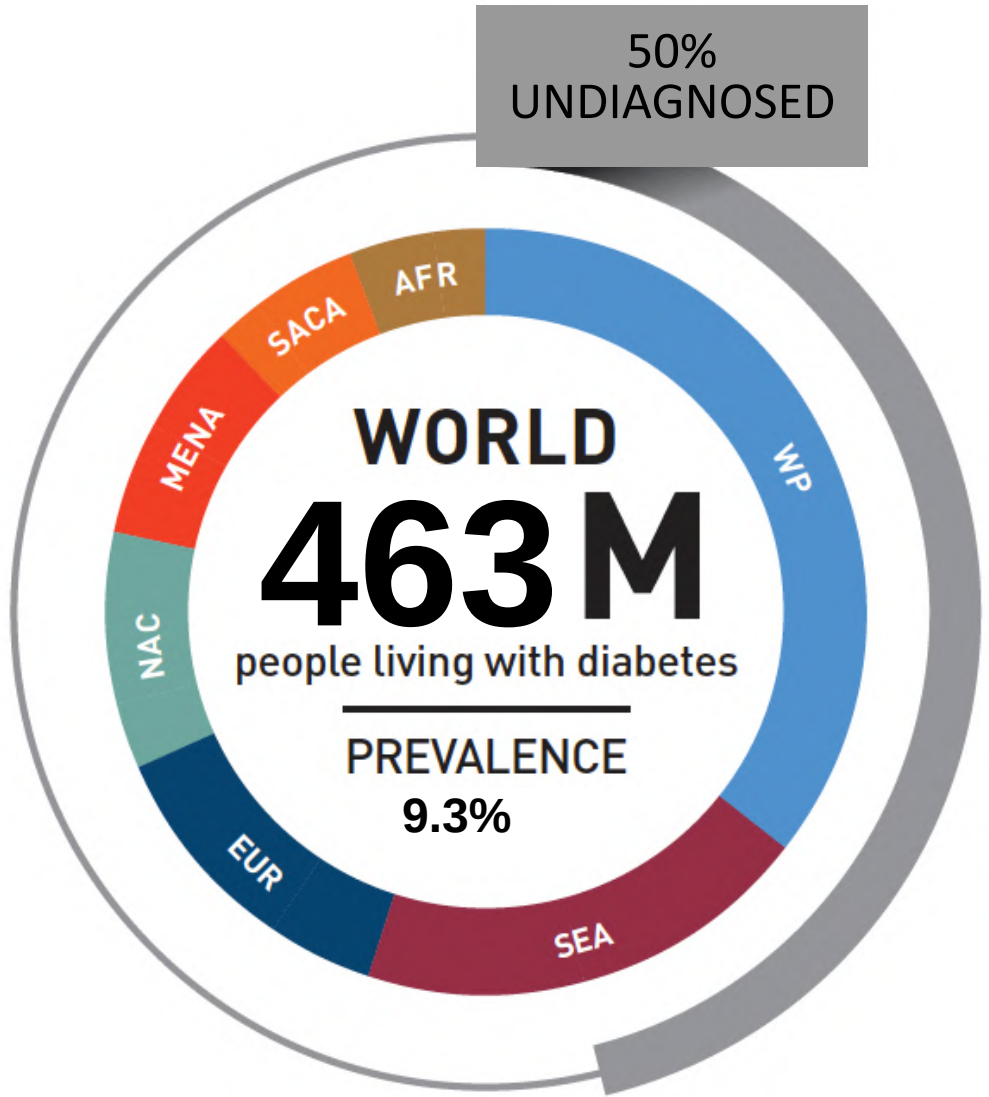
- 1 in 3 adults with diabetes currently have chronic kidney disease (CKD)



- There is no early warning - kidney function can fall below 15-20% with no symptoms
- Current standard-of-care tests cannot predict the onset of diabetic kidney disease
- Diabetic kidney disease leads to renal failure which requires dialysis (US\$72,000 p.a.) or kidney transplant
- Total cost of diabetic kidney disease = US\$130 Bn per year in USA alone

THE SOLUTION

- 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



Targeting Type 2 Diabetes (~90% of diabetics)

International Diabetes Federation 2019
US Renal Data System 2020

PromarkerD is Revenue Ready



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

Significant Unmet Need	✓	463m adults have diabetes globally - 1 in 3 currently have DKD
High Statistical Performance	✓	Peer reviewed publications – Clinical & Analytical validity proven
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 Collaboration	✓	Janssen (J&J) - global multi-centre clinical study - assessing treatment
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



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PromarkerD in the Clinic

EXISTING STANDARD-OF-CARE CANNOT PREDICT DIABETIC KIDNEY DISEASE (DKD)

PromarkerD tested on **over 5,000 patients** in 4 yr clinical studies

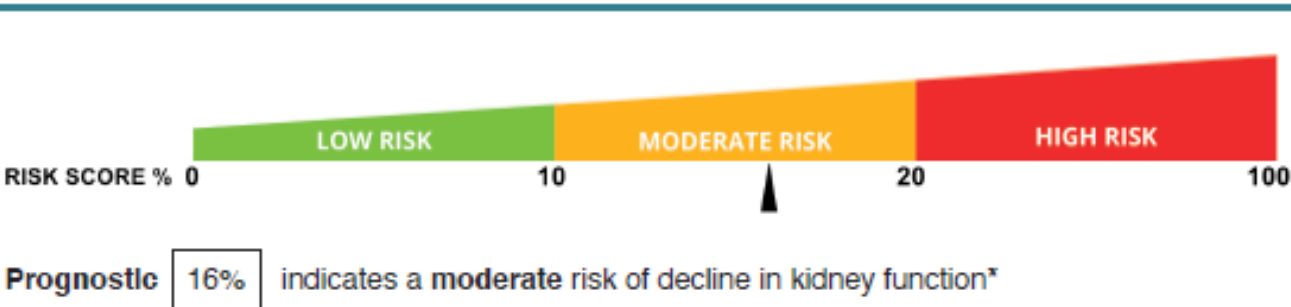
A **simple blood test** that measures three plasma proteins combined with three clinical factors (age, cholesterol, eGFR); advanced cloud-based algorithm employs a traffic light scoring system for optimal test performance

Australian clinical studies: PromarkerD **predicted 86%** of otherwise healthy diabetics who went on to develop chronic kidney disease ('incident DKD') within 4 yrs [Diabetes Care (2017), J Diabetes Complications (2019)]

Global clinical study - Janssen (J&J) collaboration: Stage 1 - PromarkerD predicted incident DKD in the completed CANVAS clinical trial; high-risk patients **13.5 times more likely** than low-risk to develop DKD ($P = 1.3 \times 10^{-104}$) [J Clinical Medicine (2020)]

Global clinical study (Janssen): Stage 2 (in progress) – Assessing the drug treatment effect of canagliflozin versus placebo on PromarkerD risk scores: Do 'at-risk' patients continue to decline, or stabilize, or recover?

TEST RESULTS



* 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)

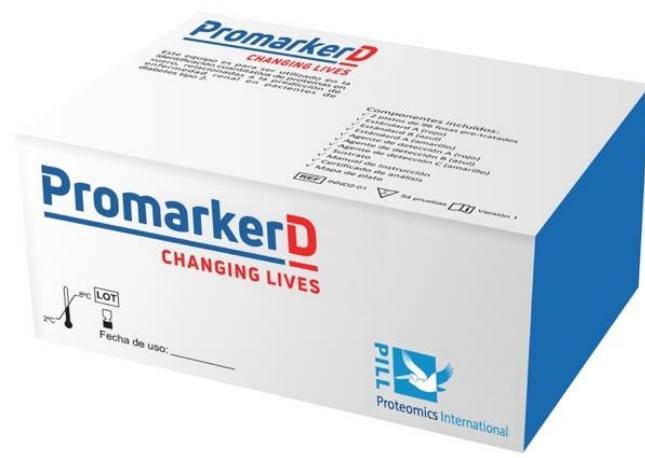
PromarkerD - Route To Market



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OUT-LICENSING MODEL for Clinical Pathology Laboratories

- PIQ licences test to be run in approved lab
- PIQ supplies the product to the lab at cost
- Lab conducts tests and submits raw data to the PromarkerD hub (cloud server)
- PromarkerD algorithm calculates risk score (Low, Moderate, High) and returns report to lab
- Lab pays PIQ a royalty per test



IN VITRO DIAGNOSTIC TEST (IVD)

- Immunoassay **kit** standard to clinical pathology laboratories
- CE Mark (EU) approved
- Manufacturing scale-up in progress

NEW MARKET: ITALY

- **First licence agreement for high throughput immunoassay – October 2020**
 - 3.7m people in Italy have type 2 diabetes (1 in 12)
 - Initial 2 yr agreement with innovative Italian distributor Medical Horizons SRL
 - Key Opinion Leaders (KOL's) driving awareness and understanding of PromarkerD's benefits
 - *Test registered for use with Italian Ministry of Health*
 - *Sales expected 1H CY21*

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 \$150**

[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 & 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.

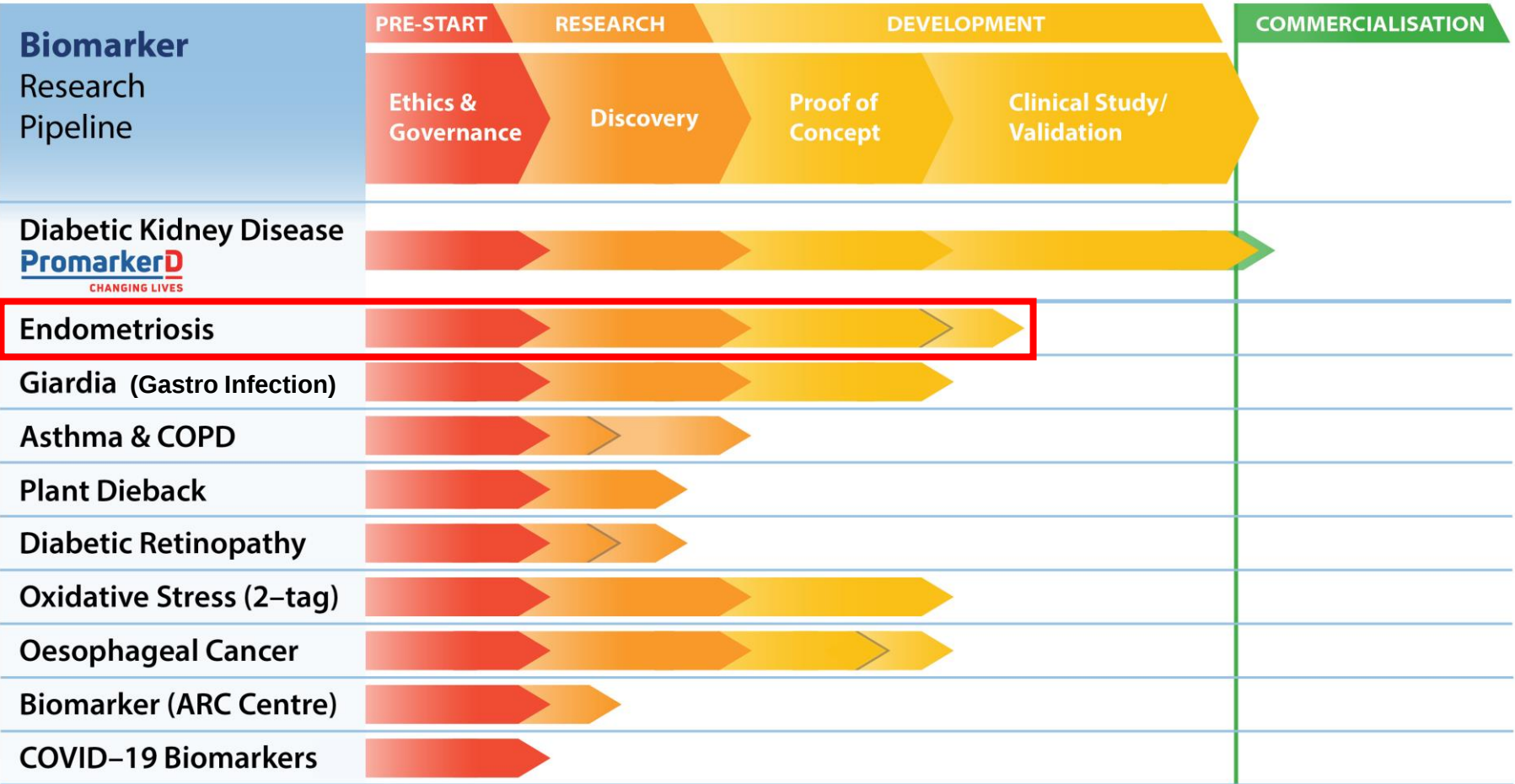
⁴ USA patent further extended to cover method for identifying drugs for abnormal kidney function using one of the PromarkerD biomarkers (CD5L).

Diagnostics Pipeline

Further Global Potential in New Markets

- ▶ Employs the Promarker™ technology platform to develop novel intellectual property
- ▶ Targeting new diagnostic tests in areas of significant unmet need
- ▶ **Global 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 simple blood sample test for endometriosis
- ▶ Proof of concept study performed on 54 women returned statistically significant results
- ▶ Patent filed for new invention
- ▶ *Finalising an agreement to access a large patient cohort for the clinical validation study*



Promarker™ Timeline & Upcoming Milestones

Two year targets and achievements

November 2018

Proteomics enters PromarkerD collaboration with US big pharma Janssen Pharmaceuticals

September 2019

PromarkerD immunoassay development completed & test validated

September 2019

PromarkerD clinical validation results published

February 2019

Proteomics commences manufacture of PromarkerD as immunoassay (IVD)

November 2019

CE Mark for PromarkerD predictive test for diabetic kidney disease

March 2020

Proteomics patents biomarkers for diagnosis of endometriosis

January 2020

PromarkerD software algorithm receives CE Mark

April 2020

CE Mark for PromarkerD immunoassay Kit

June 2020

Big pharma (Janssen) clinical study validates PromarkerD kidney test

16 October 2020

First distribution agreement for PromarkerD immunoassay - Italy

9 October 2020

Partnership with QIMR Berghofer Institute targets oesophageal cancer

12 November 2020

Second distribution agreement for PromarkerD immunoassay – Israel

2021 targets

Additional Licensing deals for PromarkerD with diagnostic, pharmaceutical, or services providers

Results from the Stage 2 study with Janssen

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

Reimbursement (Medicare) Code in the USA

First Sales of PromarkerD immunoassay

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

SHARE PRICE CATALYSTS 2021

MILESTONE		CY'21					IMPACT
		Mar'Q	Jun'Q	Sep'Q	Dec'Q	CY'22	
PromarkerD							
	Further Licensing Deals						Drive global uptake and future revenue
	First Sales						Drive revenue
	Janssen Stage 2 Results						Drive industry awareness & market demand
	FDA Regulatory Approval						Build user confidence in product & assist 2nd phase of test roll-out
	Regulatory Approvals (other)						Assist regional roll-out
	US Reimbursement Code						Secures payer approval & market demand
Promarker™							
	Endometriosis Update						New first-in-class diagnostic test/Validates pipeline
	Giardia Update						New first-in-class diagnostic test/Validates pipeline
	Diagnostics pipeline updates						Potential proof of concept results/new IP
Analytical Services							
	New Contracts						Off-set cash burn & engages potential future industry partners



Peer Comparison

		Stock Code	Company Focus	Market Capitalisation	Share Price	FY20 Revenue	FY20 Net Profit/Loss
	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.	£632m + US\$173m (~A\$1.35Bn)	880p & US\$28.00	N/A	US\$9.3m loss
	Genetic Signatures	GSS.ASX	Specialist molecular diagnostics (MDx) for the routine detection of infectious diseases. High volume and rapid tests. COVID-19 Focus.	A\$229m	A\$1.61	A\$11.3m	A\$2.0m loss
	Bard1 Life Sciences	BD1.ASX	Early stage in-licensed IP for various cancer diagnostics.	A\$225m	A\$2.81	N/A	A\$3.2m loss
	Rhythm Biosciences	RHY.ASX	Pre-commercialisation proteomics derived diagnostic test for colon cancer licensed from CSIRO.	A\$287m	A\$1.43	N/A	A\$4.0m loss
	Proteomics International Laboratories	PIQ.ASX	Predictive blood test measuring novel protein biomarkers for DKD; simple, cost effective, commercial ready. Pipeline of novel diagnostic tests in development for chronic diseases.	A\$118m	A\$1.13	A\$3.0m	A\$1.7m loss

Source: Bloomberg, company filings. Market data as at 4 March 2021, exchange rates of AUDGBP 0.56 and AUDUSD 0.78

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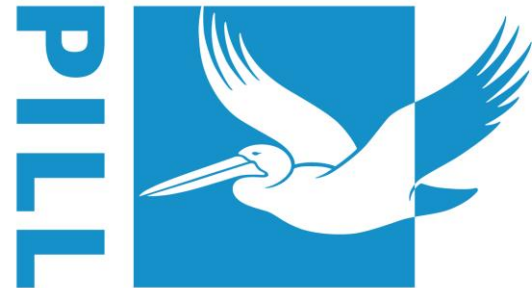
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