

# Proteomics International

LABORATORIES LTD

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Shareholder Presentation

Annual General Meeting

| Perth, WA

| 28<sup>th</sup> November 2017

**Global leader in  
predictive diagnostics  
& analytical services**

**ASX: PIQ**



# Disclaimer & forward-looking statements

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# PIQ in brief



- ▶ Specialist **MedTech and Life Sciences** company focused on the application of proteomics
- ▶ Revenue generating - **Est'd 2001**
- ▶ Listed on **Australian Stock Exchange** 2015 (code: PIQ)
- ▶ Western Australian **Exporter of the Year** 2016
- ▶ **World's first company** to receive ISO 17025 laboratory accreditation for proteomics services
- ▶ Proven technology with established IP
- ▶ Operates from purpose built, **state-of-the art facilities** in Perth, Western Australia
- ▶ **Product commercialisation on track**
- ▶ **Revenue streams growing**



Quality is Assured



# Corporate overview

Capital Structure	
ASX code	PIQ
Shares on issue	59m
Market capitalisation (@ 18c)	\$10.6m
Listed (@ 20c); raised \$3m	Apr 2015
Placement/SPP (@ 24c); \$2m	Dec 2016
12 month price range	28c-15c

Shareholders	
Top 20 Shareholders	63.1%
<b>Major Shareholders</b>	
Lipscombe	27.5%
Dunlop/Randolph Res PL	9.2%
XYLO PL	9.0%
HSBC Nominees	3.1%
Sparrow Holdings PL	1.8%



Dec '16

**PIQ**

Nov '17

Balance sheet and P&L	
Income 2016-17	\$1.9m (+30%)
Cash burn 2016-17	\$0.9m (- 31%)
Income 2017-18 (est.)	\$2.7m (+42%)
Cash burn 2017-18 (est.)	\$0.5m (- 44%)
Cash at Sept 30 <sup>th</sup> 2017	\$1.5m

# Business model: strategic rationale



## Three **integrated areas**

Unifying “**Promarker™**” platform technology

- leverage & efficiency

### ► **Analytical services**

Best in class **Quality Control** testing

- Biosimilars & biologics
- Pharmacokinetic (PK) testing for clinical trials

### ► **Diagnostics**

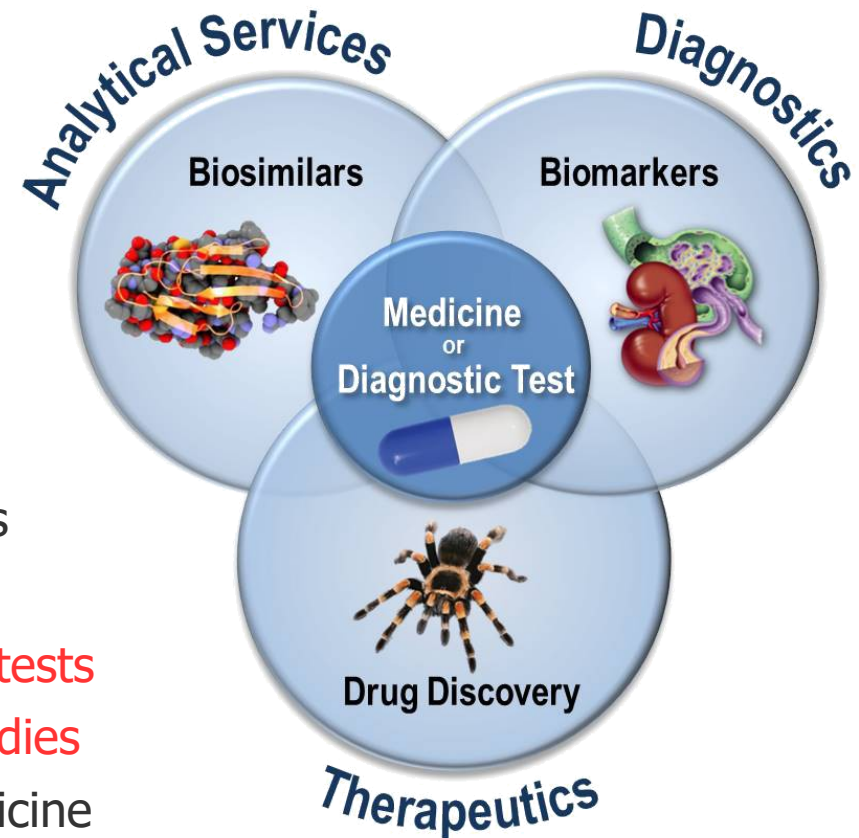
Proven technology platform to create diagnostic tests

Ability to link clinical trials & pharmacokinetic studies

- Biomarkers of disease and personalised medicine
- Proven platform for biomarker discovery & validation

### ► **Therapeutics**

- Peptide based drug discovery





## Analytical services



# Accreditation



- ▶ **World's first company** to receive ISO 17025 laboratory accreditation for proteomics services (2009)
- ▶ All sample analysis is undertaken in accordance with the standards of:  
**ISO/IEC 17025:2005 (Chemical Testing); and**  
**ISO/IEC 17025:2005 (Research and Development)**
- ▶ ISO 17025 laboratory standard ensures generation of **technically valid results**, and is the most widely used standard for USA federal testing laboratories:  
[www.fda.gov/RegulatoryInformation/Guidances/ucm125434.htm](http://www.fda.gov/RegulatoryInformation/Guidances/ucm125434.htm)
- ▶ The management of research projects is conducted in accordance with the **OECD Principles of Good Laboratory Practice**
- ▶ The facilities, methods and protocols used are assessed by NATA every 18 months providing **facility wide accreditation**



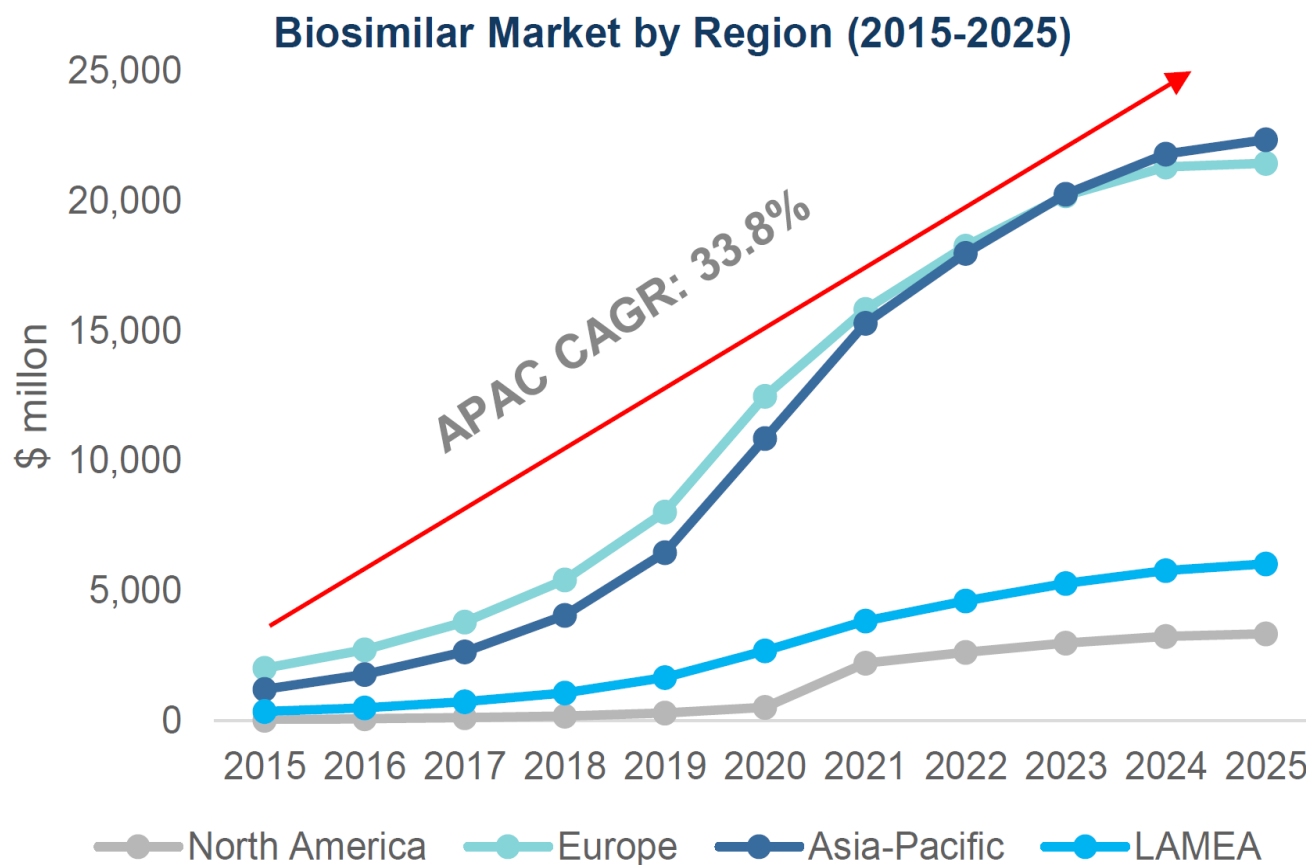
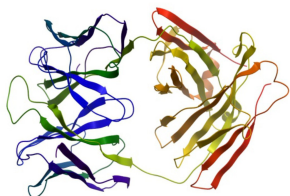
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# Fast growing biosimilars market



## Analyses required to demonstrate biosimilarity

- Protein sequence mapping
- Intact mass determination
- N/C-terminal sequencing by mass spectrometry
- N-terminal (Edman) sequencing
- Amino acid analysis
- Disulphide mapping
- Impurity profiling (Met oxidation and deamidation)
- PEGylation analysis
- Glycosylation analysis
- Aggregation analysis by analytical ultracentrifugation
- Circular dichroism and X-ray crystallography
- Stability testing of new drug substances and products





## Diagnostics & Biomarkers



# Promarker™ platform technology

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Unique protein biomarker  
'fingerprints'



Identification of Disease or  
Condition

# Case study – the PromarkerD success story

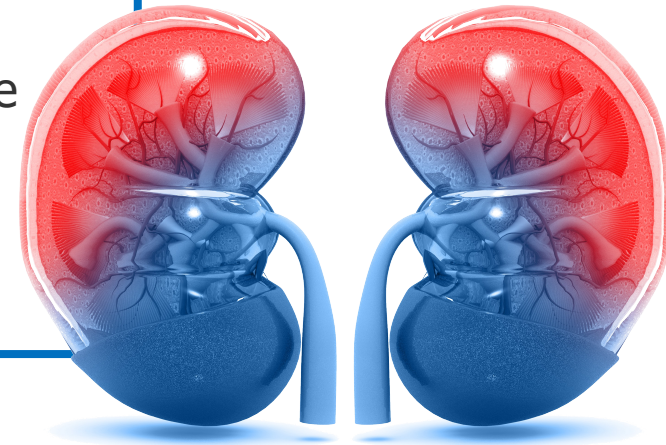


## The Problem

**422 million people** globally have diabetes (World Health Organisation)

**1 in 3 diabetic adults have chronic kidney disease** (US Centre for Disease Control)

- ▶ There are no early symptoms of diabetic kidney disease
- ▶ There is currently no available test for predicting the onset of diabetic kidney disease



## The Solution

### 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*

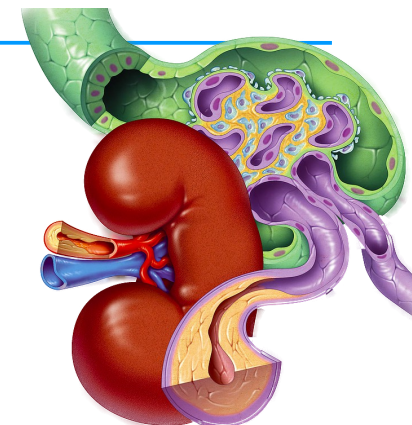
# PromarkerD – key findings

Diabetes Care Publish Ahead of Print, published online August 29, 2017

## Identification of Novel Circulating Biomarkers Predicting Rapid Decline in Renal Function in Type 2 Diabetes: The Fremantle Diabetes Study Phase II

<https://doi.org/10.2337/dc17-0911>

Kirsten E. Peters,<sup>1,2</sup> Wendy A. Davis,<sup>1</sup>  
Jun Ito,<sup>2</sup> Kaye Winfield,<sup>2</sup> Thomas Stoll,<sup>2</sup>  
Scott D. Bringans,<sup>2</sup> Richard J. Lipscombe,<sup>2</sup>  
and Timothy M.E. Davis<sup>1</sup>



**Patent No.: US 9,146,243 B2**

**Date of Patent: Sep. 29, 2015**

**METHOD OF ASSESSING DIABETIC NEPHROPATHY USING CD5 ANTIGEN-LIKE**

**Inventors:** Thomas Stoll, Windorf (DE); Scott Bringans, Harrisdale (AU); Kaye Winfield, Bayswater (AU); Tammy Casey, Mount Pleasant (AU); Wendy Davis, Cottesloe (AU); Kirsten Peters, Wellard (AU); Timothy Davis, Cottesloe (AU); Richard Lipscombe, Floreat (AU)

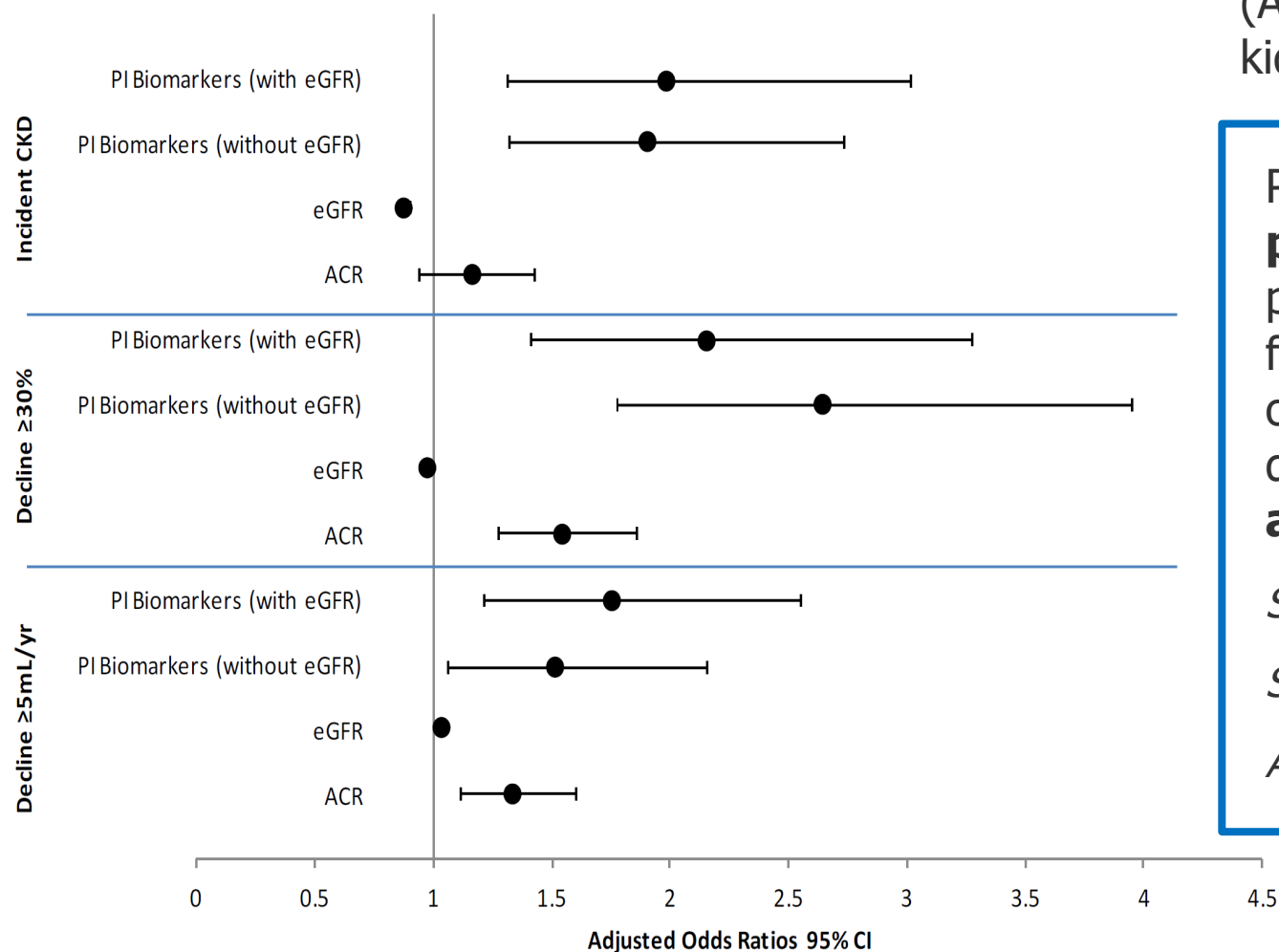
## EuPA Open Proteomics 14 (2017) 1–10

Comprehensive mass spectrometry based biomarker discovery and validation platform as applied to diabetic kidney disease

Scott D. Bringans<sup>a,\*</sup>, Jun Ito<sup>a</sup>, Thomas Stoll<sup>a</sup>, Kaye Winfield<sup>a</sup>, Michael Phillips<sup>b</sup>,  
Kirsten Peters<sup>a,c</sup>, Wendy A. Davis<sup>c</sup>, Timothy M.E. Davis<sup>c</sup>, Richard J. Lipscombe<sup>a</sup>

# PromarkerD versus current tests

## Adjusted Odds Ratios for Markers of Renal Decline



Current 'gold standard' tests (ACR or eGFR) cannot predict kidney decline

PromarkerD can correctly **predict 86%** of the previously kidney disease-free diabetic patients who go on to develop chronic kidney disease up to **4 years in advance**

*Sensitivity 86%*

*Specificity 78%*

*AUC 0.88*



# Commercialisation on track

PromarkerD Milestones	2017-18			
	Jul-Sep	Oct-Dec	Jan-Mar	Apr-Jun
<b>IP protection and KOL engagement</b>				
Key patents secured and extended <sup>1</sup>	✓	✓		
Predictive test clinical study results published	✓			
<b>IVD roll-out (Dominican Republic)</b>				
Prototype kit manufacture complete	-- -- --	-- ✓		
First commercial sales of IVD		--	■	
Milestone payment for first commercial sales			■	
<b>Licensing</b>				
First licensing deal/partnership for LDT		-- ■		
First licensing deal/partnership for CDx		■		
Second licensing deal for IVD			■	

<sup>1</sup> Patents for DKD were first granted in the USA, Singapore and Australia in 2015, and in China and Russia in 2016; other jurisdictions remain pending. An expansion of the PromarkerD patent to all kidney disease was granted in the USA in August, and in Australia in November.

-- Original target | ✓ Completed



## Pharmacokinetic testing (PK) for clinical trials



# Pharmacokinetic testing (PK)



## Revenues have commenced

- ▶ **Pre-clinical and clinical** quantitative assays for any investigational drug product
  - Accurate and precise
  - Large and small molecules
  - Leverages a wealth of expertise in building novel assays
  - High throughput robotics and high end LCMS capabilities
  - Fast turn around
  - Quality guaranteed

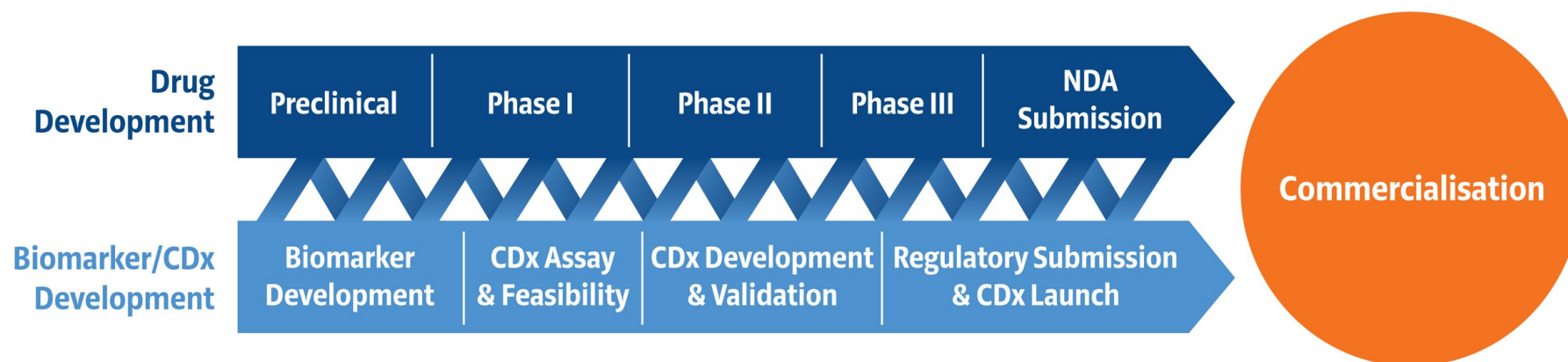


# Value proposition: synergies in combining diagnostics and clinical trials



- **Australia is a global leader in clinical trials**

- ▶ In 2016 there were over 1500 clinical trials run in Australia-NZ
- ▶ Efficient regulatory framework | High quality trial sites | Results accepted globally



- **Companion Diagnostics (CDx) are a key tool to develop drugs more efficiently**

- ▶ The FDA states a Companion Diagnostic.... provides information that is essential for the safe and effective use of a corresponding drug or biological product
- ▶ Identify patients in need | More accurate dosing | Monitor side effects | Improved success rate

**Partner capabilities uniquely link clinical trials and diagnostic test development**

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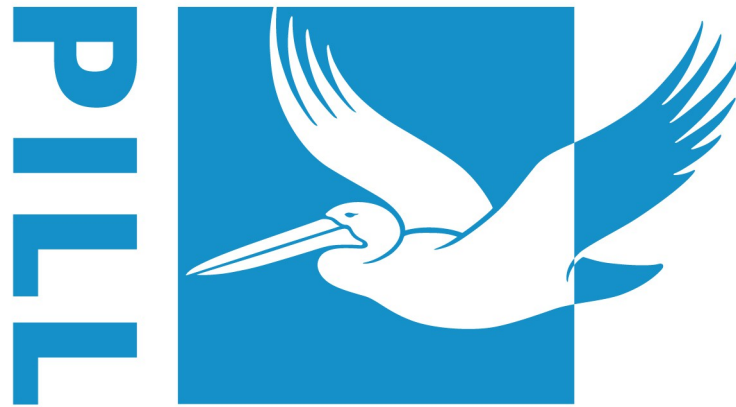
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