

# Proteomics International

LABORATORIES LTD

Investor Presentation - Canary Capital | 8 February 2018

**Alliance with CPR Pharma Services** 

Improving Drug Development

**ASX: PIQ** 



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## Alliance highlights: Summary



- Proteomics International Laboratories Ltd (PIQ) is to collaborate with CPR Pharma Services (CPR)
  - ▶ PIQ is a world leading specialist laboratory and diagnostics developer
  - CPR is a regional leader in provision of clinical services and laboratory testing in clinical trials
- To produce a unique, R&D focused, Contract Research Organisation (CRO) capability specialising in diagnostics, clinical trials, and precision medicine
  - Most advanced bioanalytical laboratory group in Australasia
  - ▶ Global leader in the analysis of biologics/biosimilars the fastest growing drug sector globally
  - Ability to develop and deliver the next generation of diagnostic tests (Companion Diagnostics)

## Alliance highlights: Key benefits



### The commodity: Diagnostic and Analytical tests for precision medicine

The combined capabilities of Proteomics International Laboratories Ltd (PIQ) and CPR Pharma Services (CPR) are expected to create:

\$

Immediate cost benefits to streamline business development and efficiencies in laboratory activities

\$\$

 A globally competitive and regionally dominant player for clinical trials and bioanalytical laboratory testing

\$\$\$

 Expertise & critical mass in biosimilars characterisation and analysis to service the demand for high-value clinical trials of biosimilars

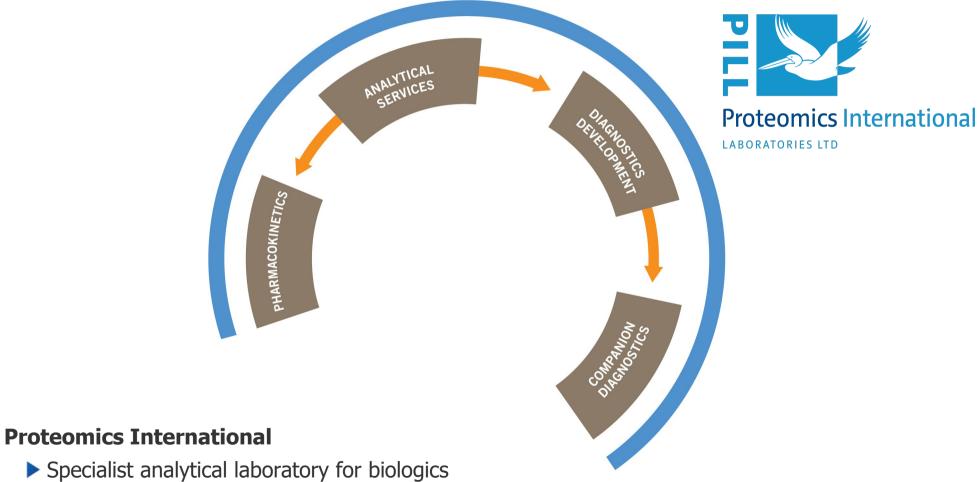
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Leverage to attract clients for, and to create or sell, new companion diagnostic tests essential for the safe and effective use of a drug, namely applying precision medicine to shorten the drug development process



## Strategic rationale: supply chain

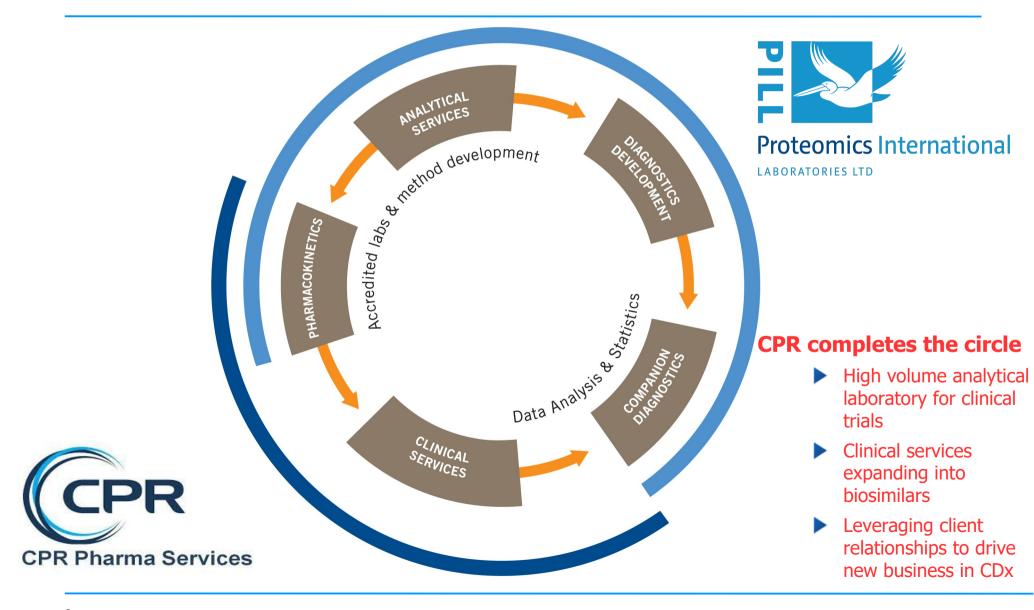




- ▶ Proven platform technology for developing new methods and novel diagnostic tests

# Strategic rationale: supply chain completed





### Strategic rationale: the Alliance

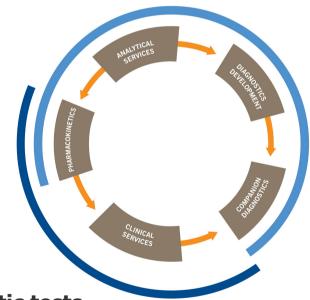


### World class bioanalytics lab

- Expert in accredited analysis of biosimilars and biologics
- Specialist in method development for analytics and diagnostics
- Specialist, accredited pharmacokinetic (PK) testing for pre-clinical and clinical trials

### Globally recognised CRO for clinical services

- Full service early phase clinical trials specialist
- FDA and EMA inspected
- ► Highly qualified Quality Assurance department
- Strong client relationships in US and Asia



### Expertise at the forefront of the next generation of diagnostic tests

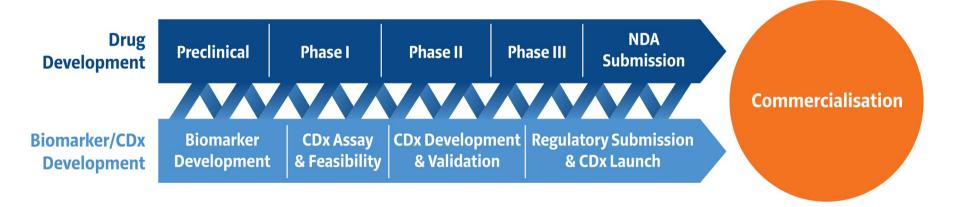
- ▶ Developed PromarkerD a world first predictive diagnostic test for diabetic kidney disease
- Proven platform technology for developing new diagnostics and Companion Diagnostics (CDx)

# Value proposition: Synergies in combining PIQ diagnostics and CPR 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

- Validated biomarkers can be commercialised as diagnostic kits, including use in clinical trials to measure and monitor effectiveness, or toxicity of a drug treatment
- ▶ 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

The combined companies will uniquely link clinical trials and diagnostics development

### Recent sector transactions



### The sector is currently experiencing strong interest — all targets are Australian based

Date	Target	Buyer	Details	Financials
Aug 2017	Vivopharm	Cancer Genetics	Laboratory offering preclinical phamacology, toxicology & bioanalytics	Acquisition \$15.3m
Aug 2017	Novotech	TPG Capital	Full clinical service CRO (without a clinical trial site or laboratory)	Acquisition \$300m
Jan 2018	Nucleus Network	Crescent Capital Partners	Clinical trials site (no laboratory)	Estimated value \$100m
Nov 2017	Rhythm Bioscience	IPO	Diagnostic test for colorectal cancer at early development stage	\$20m; heavily over- subscribed



## Experienced board & management



### Terry Sweet FAICD, Chairman

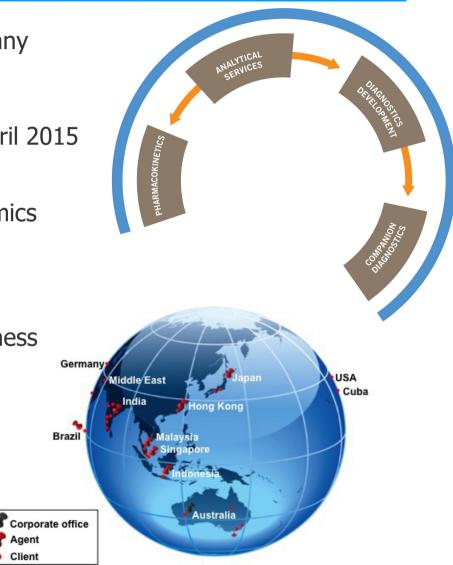
Director of several listed companies over the past 30 years in both executive and non-executive capacities. Companies include XRF Scientific Ltd, where he was Managing Director for 4 years, Western Biotechnology Ltd, Heartlink Ltd, and Scientific Services Ltd.

- Richard Lipscombe PhD (London), MA (Oxon), Founder & Managing Director Successfully managed the Company for 16 years.
   30 years experience in research and development globally in academic and commercial entities.
   Technical expertise in chemistry, immunology, & biomarker discovery.
- **John Dunlop** PhD (UWA), BSc (UWA), Non-Executive Director
  Director of several several ASX-listed companies covering mineral exploration, finance & analytical labs.
  Founding Director of beta-carotene producer Western Biotechnology Ltd and Founding Director of Sheen Analytical Services (which listed as Scientific Services Ltd).
- **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 and 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, most recently serving as MD, 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 36 years in life sciences, biotechnology, and diagnostic industries including DuPont and PerkinElmer.

### Overview: Proteomics International



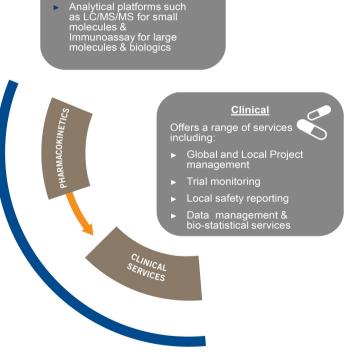
- Specialist MedTech and Life Sciences company
- Revenue generating company Est'd 2001
- Listed on the Australian Stock Exchange April 2015 (code: PIQ)
- Global leader & innovator in field of proteomics
- World's first company to receive ISO 17025 laboratory accreditation for proteomics services
- Analytics, diagnostics, and drug discovery business
- Proven technology with patents granted
- Operates from purpose built, state-of-the art facilities in Perth, Western Australia
- Asian focus with global reach



### Overview: CPR Pharma Services



- Revenue generating (FY17: \$15m) Est'd 2009
- Full service early phase (I and II) CRO
- FDA inspected with OECD GLP and ISO 17025 R&D laboratory accreditation
- Close relationship with Phase I clinical trial sites across Australia
- Serves a range of biotech and small-mid sized pharma
- Services underpinned by a **highly qualified** Quality Assurance Department
- Head-quartered in Adelaide, South Australia
- Asian and US focus



Laboratories

Offers a range of services including:

Regulated bioanalysis

## Operating in fast growing markets

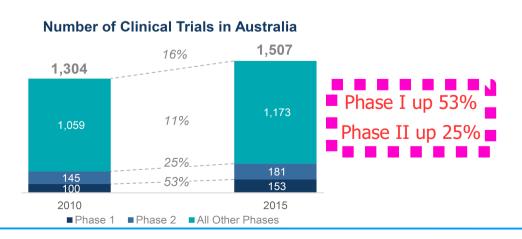


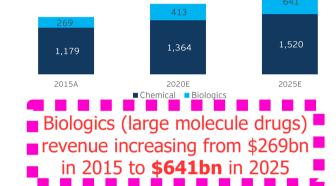
### Testing new protein drugs: biologics and biosimilars

- 7 of world's top 10 selling drugs are protein therapeutics ("biologics")
- Fastest growing class of drug in development is biologics
- Manufacture of biosimilars is growing rapidly in Asia
- Biomarkers (creating novel diagnostic tests)
  - predicted to double in size to \$45.6bn by 2020
  - with the personalised medicine market worth over \$149bn

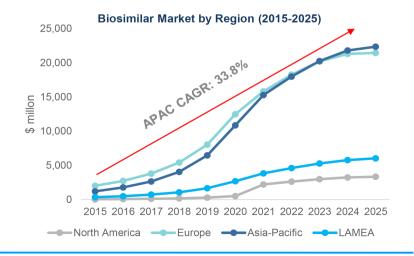
#### Clinical services

- The demand for clinical trials in Australia continues to grow
- Phase I and Phase II show strongest demand





Global Pharmaceutical market outlook



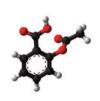
## Strategic rationale: Biosimilars testing



Protein drugs, originally termed "biologics", can perform highly complex functions that simple small chemicals cannot perform.

- Seven of the world's ten best selling drugs are protein-based drugs ("biologics")
- Generic copies of these sophisticated drugs are known as 'biosimilars'

### **Drug developments** - comparison of size and complexity



#### 21 atoms

#### **Aspirin**

analgesic first derived from tree bark.

180 atomic mass units





#### **723** atoms

#### Insulin

peptide used in diabetes management. **5,808 atomic mass units 32 x aspirin** 





#### **25,000** atoms

#### Herceptin®

engineered Monoclonal Antibody used for treating breast cancer and chronic kidney failure.

150,000 atomic mass units

850 x aspirin • 26 x insulin



### **Fast-growing markets**

biosimilars & biologics QC

clinical trials testing (pharmacokinetic studies)

- PIQ specialises in analysing biosimilars
- CPR has identified biosimilars as a growth area for clinical trials

# Case study: Building a world leading predictive diagnostic test - PromarkerD





Without PromarkerD



With PromarkerD





## Case study – the PromarkerD success story



#### The Problem

**425 million people** globally have diabetes (International Diabetes Foundation)

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

# Clinical utility: both a diagnostic (Dx) and companion diagnostic (CDx) test



### A new approach to managing diabetic kidney disease

- Product will launch in Q1 2018
- ▶ Early detection, intervention, monitoring and management
- Identify at-risk individuals

Tighter monitoring and control of blood glucose and insulin level implemented,

alongside routine PromarkerD follow-up tests

- Targeted treatments and medications
- Manage disease progression
- As an endpoint marker in clinical trials for any new drug
- For risk stratification in future clinical trials



The Promarker platform can be used to develop a CDx for any new drug

### Please contact



### **Richard Lipscombe**

Managing Director

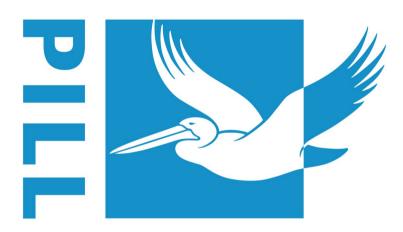
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