


# Proteomics International Laboratories Ltd PIL

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Investor Presentation | June 2015



**Global leader & innovator in the field of proteomics**

**ASX: PIQ**

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# Positioning Statement

*The Human Genome Project, to map human DNA, is the single largest undertaking in the history of biological science. Led by the US government, it was a \$US3 billion international collaboration completed in 2003 after almost two decades of planning and execution.*

*More than a decade following its delivery, cumulative benefits to the US economy are estimated to near \$US1 trillion, representing a return of 65-fold for every cent of government funding towards the initiative.*

*A next generation progression of science and technology in this area is the study of proteomics - the industrial scale study of the structure and function of proteins.*

***Proteomics International Laboratories is acknowledged as a global leader and innovator the field.***



# What is proteomics?



- ▶ Proteomics is the industrial scale study of the structure and function of proteins.
- ▶ It is an integral part of the biotechnology and life sciences industries and plays a key role in understanding disease and biological systems.
- ▶ Represents a massive global market estimated to be worth \$20.8b by 2018
- ▶ Unlike our genes, the protein make-up in our bodies changes considerably over time – eg; a cancerous cell will have significantly different proteins to a healthy cell.
- ▶ Proteomics assesses the differences in the protein make-up of people with and without a particular disease to provide diagnosis of disease and identify drugs to treat disease.

**Why study proteomics?:** *these two organisms have exactly the same genome.....*



# Corporate Overview



Capital Structure	
ASX code	PIQ
Shares on issue	~50.6m
Listed	16 April 2015
Market capitalisation (@71c)	~A\$36m
12 month price range	77.5c-18.5c
Cash on listing	Raised \$3.05m

Shareholders	
Top 20 Shareholders	70.59%
<b>Major Shareholders</b> Richard Lipscombe XYLO Pty Ltd John Dunlop Randolph Resources Pty Ltd Sparrow Holdings Pty Ltd	

Board and Management
Mr Terry Sweet, Non-executive Chairman
Dr Richard Lipscombe, Managing Director
Dr Bill Parker, Non-executive Director
Mr John Dunlop, Non-executive Director
Mr John (Chuck) Morrison, Global Head of Business Development

# Board & Management

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## **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 14 years
- ◆ 29 years experience in research and development globally in academic and commercial entities
- ◆ Technical expertise in chemistry, immunology, peptide synthesis & high performance computing

## **John Dunlop** BSc (UWA), 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)

## **Bill Parker** PhD (UWA), BSc (London), Director & Co-founder

- ◆ 30 years experience in commercial and university laboratories
- ◆ Director and founder of ASX listed Western Biotechnology Ltd (subsequently acquired by Hoffman La-Roche)

## **Chuck Morrison** Bsc (Boston), MBA (Boston), Business Development

- ◆ 36 years in life sciences, biotechnology, and diagnostic industries including DuPont and PerkinElmer

# Company Overview



- ▶ Established, revenue generating Company – Established 2001
- ▶ Global leader & innovator in field of proteomics
- ▶ 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 at the Harry Perkins Institute of Medical Research in Perth, Western Australia
- ▶ Business model uses proprietary technology platform which drives three synergistic proteomics-based business units in massive growth markets:



Quality is Assured



# Growth markets



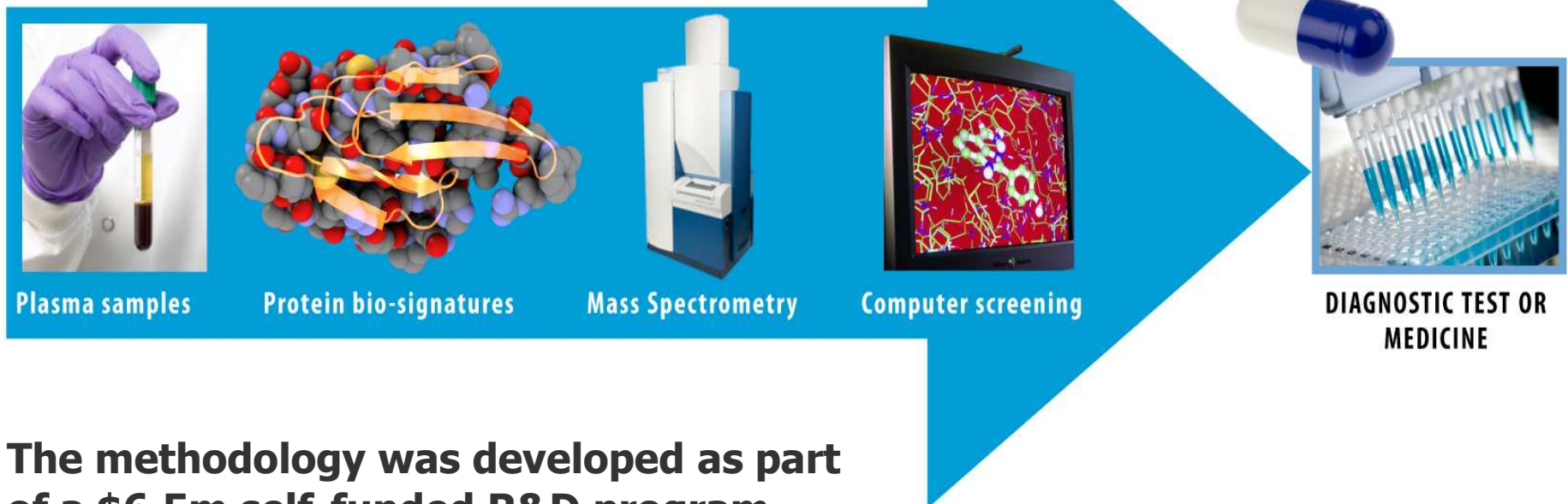
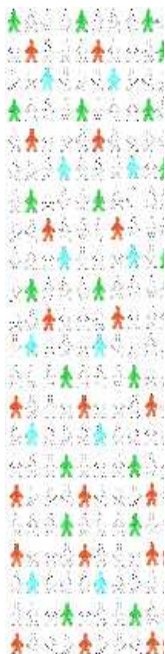
- **Diagnostics (biomarkers) market is \$17.5b**
  - ▶ predicted to reach \$40.8b by 2018
  - ▶ 'omics technology holds ~75% share
- **Proteomics market to be \$20.8b by 2018**
  - ▶ Bio-engineered protein drugs was \$152b (2013) CAGR 7.2%
  - ▶ 7 of world's top 10 selling drugs were proteins therapeutics
  - ▶ Between 2013 & 2017 drugs worth \$50b p.a. in revenues come off patent
- **Therapeutic peptide based drug market currently \$17b**
  - ▶ growing at 10% driven by genomics and 'new science'
  - ▶ better safety levels than traditional small molecule drugs



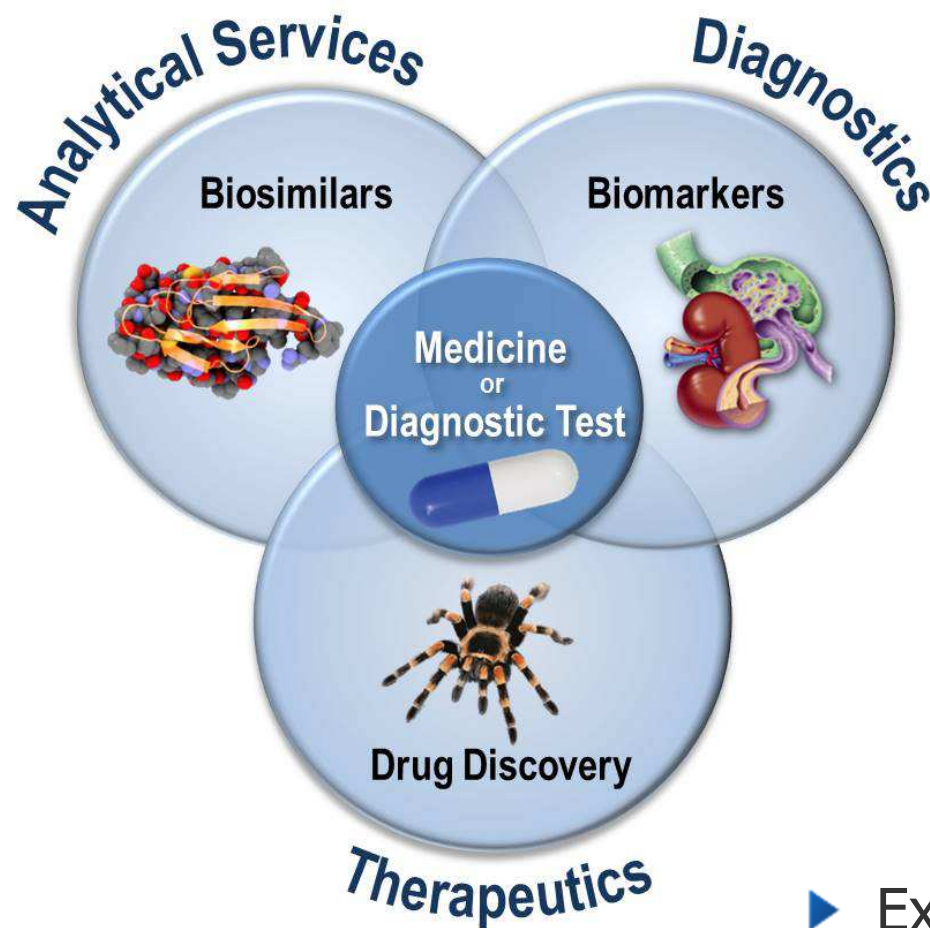
# Proprietary Platform Technology



- ▶ One proven and proprietary platform, multiple uses:
  - biomarker discovery, biosimilars testing, drug discovery



# Business model



- ▶ Three synergistic business units
  - ▶ Unifying platform technology
- ▶ Existing revenue generation & deal flow...  
Multiple major upside opportunities

# Diagnostics

*Core component of the Company's operations; focuses on utilising its proteomics-based technology platform to discover new diagnostic tests based on differences in protein make-up of people with and without a particular disease.*

*PIQ can produce a set of biomarkers to test for a particular condition, and to provide personalised medicines, rather than a one-size-fits-all approach to treatment.*

*Is not just limited to human medicine. It has widespread application, including in agriculture where, for example, it can be used to determine why a grain survives better in a particular environment.*

# Predictive test for diagnosis of Diabetic Kidney Disease

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- ▶ Company has developed and validated the world's first proteomics-derived predictive (prognostic) test for the diagnosis of diabetic kidney disease (DKD).
- ▶ Test, called PromarkerD, is a global breakthrough in the diagnosis and treatment of DKD - is currently no available test for predicting the onset of the disease.
- ▶ Diabetes is world's fastest growing health issue and largest cause of kidney disease – massive global market opportunity.
- ▶ The ability to accurately predict the onset of DKD via a simple blood test and then provide treatment to prevent onset of the disease has potential to save health care systems globally billions of dollars annually.
- ▶ Test also has a diagnostic component, in addition to the predictive application, which can diagnose the early onset of DKD where current kidney function tests fail to detect disease

# Predictive DKD test – Market potential

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- ▶ Commercial benefits, medical benefits and cost savings in commercialising the test are substantial - in Australia alone, total cost to health system and in productivity loss from diabetes estimated at \$10.3b annually.
- ▶ International Diabetes Foundation estimates 382 million people globally have diabetes - expected to rise to 1 in 10 of world population by 2035, and
- ▶ According to US Centre for Disease Control 35% of adults with diabetes have chronic kidney disease and 20% will end up with kidney failure.
- ▶ Potential for pharma companies to market test to identify at-risk patient groups and then provide drugs to treat patients may provide PIQ substantial licensing fees/royalties.
- ▶ PromarkerD may be commercialised using standard pathology laboratory assay systems – and in future via a specialist mass spectrometry test
- ▶ Companies specialising in diagnostic kits may derive revenue streams and PIQ derive licensing fees/royalties from a commercially available test
- ▶ Global diagnostic kit market is substantial; total annual revenue of US pathology laboratory industry is US\$55b, and in Australia is \$3b.



# Predictive DKD test – Background



- ▶ Test developed using PIQ's proteomics platform to measure specific biomarkers (biological signatures) in the blood of patients with diabetes to determine the likelihood of those patients contracting DKD.
- ▶ Test was developed & validated in a \$2m clinical study of 576 patients with diabetes, in WA from 2010 - 2014
- ▶ Results show PromarkerD can predict:
  - ▶ Which patients with diabetes will progress to have a significant decline in kidney function better than any other current known measure; and
  - ▶ Which people with 'normal' kidney function as measured by conventional tests are at risk of kidney problems.
- ▶ Specifically the clinical study found that 10% of patients had a significant & rapid decline in kidney function over the 4 year study period and that PromarkerD correctly predicted 67% of these individuals.
- ▶ Results have been cross-validated with an established antibody-based technique broadly accepted by the US Food and Drug Administration (FDA) – and showed excellent correlation between the two methods.

- ▶ Agreement with major Chinese biopharmaceutical company, Newsummit Biopharma Co., to commercialise the test in China.
- ▶ Agreement is PIQ's first commercial agreement for the test.
- ▶ Under the Agreement, PIQ is working with New Summit Bio to manufacture the test kit and seek licensing partners to commercialise it in the Chinese market.
- ▶ China represents a key market for PIQ;
  - ▶ Incidence of diabetes has increased dramatically in China in recent years, and
  - ▶ diabetes has been declared one of the Chinese Ministry of Health's four pillars for investment, with hundreds-of-millions-of-dollars to be invested over the next few years.

# Additional Diagnostic Targets

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- **Other diabetes complications**

- ▶ Heart disease
- ▶ Loss of eye sight
- ▶ Poor circulation leading to amputations

- **Alzheimer's disease**

- ▶ In the USA, one-in-nine people over 65 suffer from the condition
- ▶ Annual cost of caring for Alzheimer's patients estimated at \$220b

- **Veterinary**

- ▶ Detecting parasites in dogs

- **Crops**

- ▶ Selecting strains resistant to salination

# Analytical Services

*PIQ's Analytical Services business is built around its proteomics technology platform's ability to test & validate the protein composition of a wide and varied range of products. It has major application in the generic drug market (bio-similars) with manufacturers of generic drugs seeking to have their compounds validated as like-for-like against blockbuster drugs they seek to replace as they come off patent.*

*12 protein-based drugs with combined revenue of \$50b will come off patent by 2017. The composition of these bio-similars requires rigorous testing prior to receiving regulatory approval for commercial use and PIQ offers one of the world's only accredited laboratories in the world for this type of analytical testing.*

# Analytical Services

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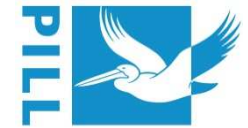


## Proven track record in analysing protein drugs

- ▶ Blue chip, global client base.
- ▶ Analytical & consulting services growing >30% per year.
- ▶ PIQ is one of the few companies worldwide with international accreditation.
- ▶ Latest US FDA guidance (May 2014) for biosimilars (generic protein drugs) recommends extensive and robust comparative structural studies – will drive demand for services.
- ▶ Recently partnered with global CRO, inVentiv Health Clinical – this is driving global reach.
- ▶ Significant opportunity to service fast growing generic drug manufacturing industry – Indian companies leading the boom.
- ▶ Network of distributors to help roll-out.
- ▶ Major contracts post listing: a2 Milk Company and Major biopharmaceutical company.



# Analytical Services – Clients & partners



An array of blue chip, international clients and partners have contributed to a growing client base and sustained income for 14 consecutive years



# Proteomics sector transactions



- **Proteome Sciences** (AIM: PRM)
  - ▶ biomarker discovery, validation and assay development in Alzheimer's, breast cancer & cosmetics
  - ▶ revenue up **86% in 2013** to **GBP2.14m**; **mkt cap \$100.8m** (1 Feb 15)
- **Applied Proteomics Inc**, private San Diego-based company
  - ▶ biomarker discovery focused on colorectal & pancreatic cancer
  - ▶ **raised \$28m** in Aug 2013 from Malaysia's Genting Berhad, Domain Associates and Vulcan Capital; **raised \$22.5m** in 2012
- **Caprion Proteomics**, Canada
  - ▶ biomarker discovery and immune monitoring in diabetes, oncology & infectious diseases
  - ▶ Thallion Pharmaceuticals sold Caprion Proteomics to Capital Growth Partners in 2011 in a deal valued at **\$28m**

# Sector transactions



Year	Target	Buyer / Licensor	Details	Financials
2012	Cellzome	Glaxo SmithKline	Cellzome's proteomics technologies used in drug discovery in cells and patient samples	<b>Total buyout - \$99m</b>
2012	Kforce Clinical Research	inVentiv Health	Functional outsourcing and CRO services	<b>Total buyout - \$50m</b>
2011	Zinfandel Pharma	Takeda	TOMM40 assay as a biomarker for the risk of Alzheimer's disease	<b>\$9m upfront; \$78m for development milestones</b>
2012	Proteome Sciences	Randox Laboratories	Stroke biomarkers offering early clinical diagnosis	<b>\$1m milestone, plus royalty stream</b>

Key: **Analytical services/Platform technology** | **Diagnostics**

# Intellectual property



- PILL **protects its know-how** and expertise to ensure it remains a substantial source of competitive advantage
- All biomarker and drug leads discovered using the platform technology will be protected by **global patenting** as a prerequisite for out-licensing activities
- The panel of **diabetes biomarkers is patent pending** with national phase examination accepted in Australia; in progress for Brazil, Canada, China, Europe, India, Indonesia, Japan, Russian Federation, Singapore and USA
- The Company has a patent portfolio covering its **specialised methodology** developed over the last 14 years



"Methods for determining the redox {oxidation} status of proteins"			
Country	Patent number	Status	Expiry date
Australia	2006317516	Granted	21Nov 2026
USA	8043824	Granted	8 July 2028
"Biomarkers associated with pre-diabetes, diabetes and diabetes related conditions"			
Derived from International Patent Application PCT/AU2011/001212			

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