



Proteomics International

LABORATORIES LTD

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Proteomics International becomes world's most accredited protein testing laboratory, launches pharmacokinetic and companion diagnostic testing for clinical trials

Proteomics International Laboratories Ltd (ASX: PIQ) has become the most accredited protein testing company in the world with the award of ISO 17025 Research & Development certification, which includes compliance with the OECD Principles of Good Laboratory Practice (GLP). This extends the company's existing certification for ISO 17025 in the field of Chemical Testing.

- New certification solidifies Proteomics International's status as world's most accredited protein testing laboratory
- Launch of comprehensive suite of new pre-clinical and clinical testing capabilities: pharmacokinetic (PK), pharmacodynamic (PD), and companion diagnostic (CDx) services
- Accreditation guarantees highest quality of data for clinical trials, biomarker discovery, biologics and biosimilars testing

The accreditation serves as a springboard for the launch today of new analytical services for the drug development pipeline. The specialist services target pre-clinical and clinical trials by providing pharmacokinetic testing and development of companion diagnostics based on the company's Promarker™ platform.

With this accreditation Proteomics International sits alongside the world's trusted laboratories and cements the company's position as a global leader in specialist biochemical testing.

Proteomics International managing director Dr Richard Lipscombe said we are bringing our world leading reputation for quality analytical testing in proteomics and biopharmaceuticals (biologics and biosimilars) to the broader drug development pipeline.

Asia is now the preferred destination for clinical trials, but there has been a shortage of analytical laboratories servicing the large number of clinical trial centres. There were over 1500 new clinical trials registered in Australia and New Zealand in 2016. The most common type is a Phase I clinical trial, which proves safety, and typically costs \$0.5-\$2 million dollars.

"Clinical trials are an area of great Australian strength and we're proud to become one of only three companies based in the country to offer clinical trial PK testing services," Dr Lipscombe said. "Approximately 10% of clinical trial costs are related to analytical testing and consequently these new services are expected to add significantly to our analytical business", he said.

"We wanted to ensure our clients could be confident in receiving the highest quality data, and our world-leading accreditation is a testament to the lofty standards we set."

The accreditation will further boost Proteomics International's current analytical services to the multi-billion dollar biopharmaceuticals industry, which is the fastest growing class of drugs globally.

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About Pharmacokinetic testing, Companion diagnostics and ISO 17025 accreditation

Pharmacokinetics (PK) is the study of how the body affects a drug, whereas pharmacodynamics (PD) and companion diagnostics (CDx) profile patient response to treatment by measuring markers in the blood. Together they monitor response to a new drug and in the future may help doctors develop personalised treatments.

Proteomics International's expertise in diagnostics and analytical testing allow the company to go beyond traditional PK analysis to also offer the development of companion diagnostics using its Promarker™ biomarker discovery platform.

Companion diagnostics are biomarkers that can help identify patients who are most likely to benefit from specific treatment strategies. Biomarkers can also enable the identification of people who are likely to experience the adverse effect of clinical treatment.

The combined ISO 17025 accreditations with compliance to Good Laboratory Practice (GLP) relate to both quality assurance and the traceability of samples once they come into Proteomics International's state-of-the-art laboratories located in Perth, Western Australia.

It is comparable to the standard adhered to by forensic laboratories to ensure tests on evidence from crime scenes is able to stand up to interrogation in court, and is the most widely used accreditation standard by US federal testing laboratories.

The latest accreditation comes after Proteomics International was the first laboratory in the world to receive ISO 17025 accreditation for proteomics services in 2009. Proteomics International was accredited by Australia's National Association of Testing Authorities (NATA), the world's first comprehensive laboratory accreditation body, and still one of the largest.

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About Proteomics International Laboratories (PILL) (www.proteomicsinternational.com)

Proteomics International is a wholly owned subsidiary and trading name of PILL (ASX: PIQ), a medical technology company focused on proteomics – the industrial scale study of the structure and function of proteins. In the last few years, proteins have become the drug class of choice for the pharmaceutical industry because of their intimate role in biological systems. Thus proteomics technology is now playing a key role in understanding disease, from finding new diagnostic biomarkers to determining drug targets, and discovering new biopharmaceutical drugs.

PILL is recognised as a global leader in the field of proteomics. It received the world's first ISO 17025 laboratory accreditation for proteomics services, and operates from state-of-the art facilities at the

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Harry Perkins Institute of Medical Research in Perth, Western Australia. The company's business model harnesses its proprietary technology platform to work across three integrated areas, each massive growth markets:

- 1. Diagnostics:** Biomarkers of disease and personalised medicine - focus on diabetic kidney disease.
By 2020 the biomarkers market is estimated to double in size to \$45.6 billion, and the personalised medicine market is forecast to be worth over \$149 billion.
- 2. Analytical services:** Specialist contract research fee-for-service model – focus on biosimilars QC.
The global biosimilars market is expected to reach \$6.2 billion by 2020, almost trebling from its 2015 level, as it seeks to replicate the multiple billion dollar blockbuster drugs that are coming off patent.
- 3. Drug discovery:** Therapeutic peptide drug discovery - focus on painkillers and antibiotics.
The global peptide therapeutics market is currently estimated to be worth \$18 billion and is expected to increase by over 10% per year during 2016-2025.