



Proteomics International

LABORATORIES LTD

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Proteomics International achieves ISO 13485 certification: PromarkerD manufacturing update

- **ISO 13485 certification represents a stringent commitment to quality and safety standards required for manufacturing human diagnostic tests**
- **Manufacturing milestone expected to widen market opportunities for the PromarkerD test for diabetic kidney disease and underpin future regulatory approvals**
- **Certification paves the way for establishing Northern Hemisphere manufacturing of the PromarkerD diagnostic tests**
- **Manufacturing processes for PromarkerD reagents are being streamlined to facilitate scale-up of kit production**
- **Certification will also apply to Proteomics International's pipeline of other diagnostic tests under development**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) is pleased to advise it has received ISO 13485 certification, the most widely-used international standard for quality management systems in the manufacture of medical devices.

Proteomics International managing director Dr Richard Lipscombe said achieving this ISO certification was a key milestone underpinning production and future global sales of the PromarkerD test for diabetic kidney disease. *"The ISO 13485 manufacturing standard provides the foundation to regulatory requirements for medical diagnostics and has been adopted by markets including the European Union, Australia, Japan, Canada and, most recently, the United States,"* he said.

The certification is awarded to only those companies that can demonstrate an ability to produce safe, effective products that consistently meet the expectations of customers and regulators. It represents a stringent commitment to quality and safety standards in the production of diagnostic tests.

Additionally, the certification will bolster the Company's ongoing commercial discussions with global diagnostic companies and manufacturing partners.

Manufacture of the PromarkerD immunoassay kits currently occurs under licence in Australia. In order to meet Proteomics International's anticipated worldwide demand for PromarkerD, the Company has commenced discussions with selected Northern Hemisphere diagnostics manufacturers with the objective of streamlining the future production of the assay.

Production of the PromarkerD immunoassay requires specialist reagents, including synthetic protein standards and antibodies (used to detect the target protein biomarkers). As part of securing its supply chain, Proteomics International is now constructing recombinant versions of the antibodies which are more stable than those from normal antibody cell lines, and hence will provide a more consistent product over the long term. Importantly, this manufacturing process will facilitate the

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scale-up in production of the PromarkerD immunoassay reagents and kits, without impacting current regulatory approvals.

The ISO 13845 certification will also apply to Proteomics International's pipeline of other diagnostics currently under development, including tests for endometriosis and asthma. *“With the engagement of global manufacturing partners, we are building a robust framework that will help accelerate both the commercialisation of subsequent novel tests, alongside the worldwide roll-out of PromarkerD,”* Dr Lipscombe said.

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

ENDS

About PromarkerD (www.PromarkerD.com)

PromarkerD is a predictive test for the early detection of chronic kidney disease (CKD) in patients with type-2 diabetes. CKD is one of the major complications arising from diabetes and if unchecked can lead to dialysis or kidney transplant.

The patented PromarkerD test system uses a simple blood test to detect a unique ‘fingerprint’ of the early onset of disease by measuring three serum protein biomarkers, combined with three routinely available conventional clinical variables (age, HDL-cholesterol and estimated glomerular filtration rate (eGFR)).

In clinical studies published in leading journals PromarkerD correctly predicted 86% of otherwise healthy diabetics who went on to develop chronic kidney disease within four years. The PromarkerD immunoassay, the PromarkerD mass spectrometry assay, and the PromarkerD software hub have each achieved CE Mark registration in the European Union.

Further information is available through the PromarkerD web portal.

To visit the PromarkerD virtual booth please see: www.PromarkerD.com/product

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

Proteomics International (Perth, Western Australia) is a wholly owned subsidiary and trading name of PILL (ASX: PIQ), a medical technology company at the forefront of predictive diagnostics and bio-analytical services. The Company specialises in the area of proteomics – the industrial scale study of the structure and function of proteins. It received the world’s first ISO 17025 laboratory accreditation for proteomics services, and operates from state-of-the-art facilities located on Perth’s QEII Medical Campus.

Proteomics International's business model is centred on the commercialisation of the Company's world-leading test for diabetic kidney disease, PromarkerD. The Company offsets the cash burn from R&D and product development through provision of specialist analytical services, whilst using its proprietary Promarker™ technology platform to create a pipeline of novel diagnostic tests.

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