



Proteomics International

LABORATORIES LTD

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PromarkerD secures TGA approval for software IVD and Indonesian patent

- **TGA regulatory approval granted for PromarkerD software as an in vitro diagnostic (IVD) for export use**
- **The PromarkerD software hub enables the secure delivery of test results to Proteomics International's partners around the world**
- **The remote software hub provides an additional level of intellectual property security beyond the Company's comprehensive patent portfolio**
- **Patent granted for Indonesia, which has the world's 6th highest population of adults with diabetes at over 10 million**
- **PromarkerD patent portfolio now covers Indonesia, Australia, China, Europe, Japan, Russia, Singapore and USA, with other major jurisdictions pending**
- **Early detection of diabetic kidney disease by PromarkerD can help prevent the need for renal replacement therapies, potentially saving global healthcare systems billions (\$) annually**
- **Proteomics International continues to develop existing regional PromarkerD licensing agreements, whilst actively pursuing newly identified global opportunities**

Medical technology company Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) has been granted a patent for PromarkerD, the world leading diagnostic and predictive test for diabetic kidney disease, in Indonesia. Concurrently, Proteomics International has secured TGA regulatory approval for the PromarkerD software as an in vitro diagnostic (IVD) for export use.

The PromarkerD software IVD was included on the Australian Register of Therapeutic Goods (ARTG) on the 24 July 2019.

The regulatory approval covers use of the PromarkerD software algorithm across Proteomics International's different platform technologies, which include both mass spectrometry and immunoassay formats. The successful TGA approval for PromarkerD software as an IVD forms part of Proteomics International's on-going strategy to gain regulatory approvals for the pioneering test in multiple jurisdictions. Prior to these approvals, PromarkerD testing can be undertaken in CLIA Accredited Laboratories. The number of CLIA Accredited Laboratories exceed 6,400 in the US¹, providing a broad-based network of testing facilities for the commercialisation of PromarkerD.

The PromarkerD software hub enables the delivery of results of the proprietary PromarkerD algorithm to Proteomics International's partners around the world. The remote software hub provides an additional level of intellectual property security to complement patent protection of the PromarkerD biomarkers.

The Indonesian patent number W00 2013 01585 titled "Biomarkers Associated with Diabetic Nephropathy" will extend until 20 September, 2031. Indonesia has 10.3 million adults with diabetes, which ranks the nation sixth in the International Diabetes Federation estimates for diabetes burden. Given the Company's

¹ <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/Summary-Chart-1993-to-2018.pdf>

ambitions to execute licensing transactions globally, the granting of the Indonesian patent secures another potentially lucrative jurisdiction.

The Indonesian patent complements those already granted in the USA, Europe, Japan, Australia, Singapore, Russia and China. Patents remain pending in other major global jurisdictions for both diabetic and other forms of kidney disease.

As announced at the American Diabetes Association 79th Scientific Sessions in San Francisco in an interview given by Proteomics International Managing Director Dr Richard Lipscombe [ASX 7 June 2019], the PromarkerD test is due to go live in Mexico and Europe in the coming weeks. Proteomics International continues to develop existing regional PromarkerD licensing agreements, whilst actively pursuing newly identified global opportunities.

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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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