



# Proteomics International

LABORATORIES LTD

ASX Release  
24 January 2019

ASX code: PIQ

## PromarkerD US Market Update

- **Proteomics International rescinds PromarkerD exclusive licence deal with PrismHealthDx in US – negotiations brought forward with new tier 1 partners**
- **New immunoassay technology platform to accelerate PromarkerD rollout in US**
- **Clinical samples for first phase of CDx collaborative study received from Janssen Research & Development, LLC**
- **Key Opinion Leader (KOL) engagement to drive US demand for PromarkerD**

### **Prism exclusive licensing deal rescinded**

Proteomics International Laboratories Limited (Proteomics International; ASX: PIQ) has rescinded its exclusive licensing deal with medical diagnostics company PrismHealthDx (Prism) due to ongoing rollout delays. Proteomics International is now negotiating with a number of diagnostic and laboratory technology companies that offer larger markets and faster scale and deployment, including tier 1 national diagnostic groups.

Proteomics International Managing Director Dr Richard Lipscombe said the decision to break the deal was necessary after it became clear that Prism was having internal operational issues that were preventing its laboratory rolling out PromarkerD in the US.

“PromarkerD is world-beating technology and needs to get into the hands of specialists and physicians to stem the tsunami of diabetic kidney disease which is causing over 40,000 deaths per year in the US, with related healthcare spending exceeding US\$100 billion annually.”

“There is nothing else like PromarkerD available – it is the world's leading predictive test for diabetic kidney disease according to analysts in our sector.”

He said insurance companies are also keen to have the test available because it will cut dramatically the number of people who are unaware they have progressive kidney disease so they can do something about it immediately.

Dr Lipscombe said a new partner was required that had 100% commitment to a rapid rollout in the US because the market is important for the company, and the US population with diabetes deserve to know their kidney disease status.

Proteomics International's Head of Business Development, Chuck Morrison, based in Boston, is leading the negotiations which are expected to be finalised within the next few months. Any licence transaction is expected to involve up-front, milestone and royalty payments, in line with industry standards.

**Proteomics International Laboratories Ltd**

ABN 78 169 979 971

Box 3008, Broadway, Nedlands, WA 6009, Australia

T: +61 8 9389 1992 | E: [enquiries@proteomicsinternational.com](mailto:enquiries@proteomicsinternational.com) | W: [www.proteomicsinternational.com](http://www.proteomicsinternational.com)

Prism, although not one of the major diagnostic companies in the US, provided a US beach-head for Proteomics International. However, Proteomics International insisted on only a 1 year exclusivity for Prism until May 2019, which is now void.

PromarkerD is now available on dual technology platforms that can both be operated by approved laboratories known as CLIA certified (Clinical Laboratory Improvement Amendments). There are approximately 260,000 CLIA certified laboratories in the US, the majority of which have diagnostic capabilities to license the PromarkerD test.

### **Additional technology platform to accelerate PromarkerD rollout in the US**

The successful development of the PromarkerD immunoassay platform [ASX: 14 November 2018] has created new opportunities for the roll-out and licensing of PromarkerD in the US.

The immunoassay reagents can be configured into a Laboratory Developed Test (LDT) for use by certified laboratories. This parallels the LDT using the existing mass spectrometry platform, and offers a better fit for mainstream diagnostics providers where the immunoassay platform is more standard than advanced mass spectrometry technology.

The dual technology platforms offer greater choice to the large market of certified clinical laboratories that conduct these types of test.

In parallel with the fast roll-out of PromarkerD using the Laboratory Developed Test route, Proteomics International is also pursuing registration of the kit version of the test for larger scale adoption as market demand increases.

### **Janssen Collaboration**

The collaboration between Janssen Research & Development (Janssen) and Proteomics International seeks to accelerate diabetic kidney disease and heart disease drug discovery using PromarkerD.

The first phase of samples from Janssen's completed clinical trial of its gliflozon drug have now been received in the company's Perth laboratory. Proteomics International has continued to optimise the automation of the PromarkerD mass spectrometry test to enable efficient analysis of thousands of samples. The first phase of analysis will be completed over the next 6 months.

The collaboration has the potential to establish PromarkerD as a Complementary Diagnostic (CDx) test for the therapeutic treatment of diabetes complications. If successful the PromarkerD test could be expected to be used every time Janssen diabetes drugs are prescribed (becoming a gold standard test). Potentially of even greater value, PromarkerD could be used to identify specific target populations that will respond to certain diabetes treatments, thus becoming valuable to numerous pharma companies serving the diabetes sector.

### **Key Opinion Leader (KOL) engagement**

Following the key publications of the PromarkerD clinical results Proteomics International has been engaging with KOLs in the US. These KOLs represent early adopters for PromarkerD and have the potential to champion the adoption of PromarkerD in the US for a wider-scale rollout. To this end, Proteomics International is collaborating to undertake selective studies with the KOLs in the US to strengthen the association and drive demand and uptake of PromarkerD.

In addition to working with KOLs, Proteomics International has been identifying various peak bodies in the US that cater for diabetes and kidney disease sufferers. It is hoped by working with these groups that PromarkerD can exponentially grow its brand and market awareness, thereby improving people's quality of life, reducing the burden on dialysis and ultimately saving more lives.

**Proteomics International Laboratories Ltd**

ABN 78 169 979 971

Box 3008, Broadway, Nedlands, WA 6009, Australia

T: +61 8 9389 1992 | E: [enquiries@proteomicsinternational.com](mailto:enquiries@proteomicsinternational.com) | W: [www.proteomicsinternational.com](http://www.proteomicsinternational.com)

**About PromarkerD ([www.PromarkerD.com](http://www.PromarkerD.com))**

PromarkerD is a predictive diagnostic test for diabetic kidney disease. In clinical studies presented at the American Diabetes Association Annual Scientific Sessions [ASX: 10 June 2017] and published in the prestigious journal Diabetes Care [ASX: 6 September 2017], PromarkerD correctly predicted 86% of otherwise healthy diabetics who went on to develop chronic kidney disease within four years.

PromarkerD has been rated the world's leading diagnostic test for diabetic kidney disease by the global research house Frost & Sullivan in its report titled Biomarkers Enabling Diabetes and Obesity Management [ASX: 27 March 2017]. PromarkerD has received patent protection in several major jurisdictions including the USA, China, Europe, and Japan, with others pending.

Further information is available through the PromarkerD web portal.

**About Proteomics International Laboratories (PILL) ([www.proteomicsinternational.com](http://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.

**For further information please contact:**

Dr Richard Lipscombe  
Managing Director  
Proteomics International Laboratories Ltd  
T: +61 8 9389 1992  
E: [enquiries@proteomicsinternational.com](mailto:enquiries@proteomicsinternational.com)

Susan Fitzpatrick-Napier  
[Public Relations & Media Contact]  
Digital Mantra Group  
T: +61 2 8218 2144 or +1 415-951-3228  
E: [team@dmgpr.com](mailto:team@dmgpr.com)

Dirk van Dissel  
[Corporate Advisor & Investor Relations]  
Adelaide Equity Partners  
T: +61 8 8232 8800  
E: [dvandissel@adelaideequity.com.au](mailto:dvandissel@adelaideequity.com.au)