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Diagnostics R&D update: the Promarker™ Pipeline Proteomics discovers potential biomarkers for endometriosis and *Giardia*

Medical technology company Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), which pioneered the world-leading PromarkerD predictive diagnostic test for diabetic kidney disease now licenced in the USA and Mexico, is pleased to provide the following market update on its disease biomarker discovery and diagnostics development program.

- Endometriosis study to progress to proof of concept stage after discovery of candidate biomarkers associated with the disease
- Development ongoing to detect human infective strains of the Giardia parasite
- Research to continue into lung conditions
- Mesothelioma study discontinued after no novel biomarkers found

The program employs the Promarker[™] technology platform, used to create the company's pioneering PromarkerD test, to investigate protein 'fingerprints' that are seen when a disease is present. It targets new diagnostic tests for chronic diseases with unmet medical need.

DIAGNOSTICS RESEARCH AND DEVELOPMENT - THE PROMARKER™ PIPELINE



The Promarker[™] research pipeline and typical timeline is as follows:

Ethics & governance approval (3 months), Discovery (3-6 months), Proof of concept (3-6 months), Clinical studies (12 months)

Endometriosis

Status update: Discovery study completed. Proof of concept study pending.

Proteomics International has discovered several potential biomarkers in the blood that could be used to test for endometriosis. The biomarkers were uncovered in a discovery study initiated in April 2018. The research will now progress to a proof of concept study, which is able to identify candidates with greater statistical confidence. If successful, it may lead to patentable intellectual property.

Endometriosis affects one in ten women in their reproductive years (15-49) and costs \$12,000 per year for every person diagnosed. Both incidence and health burden are comparable with diabetes. This gynaecological condition causes chronic pain and infertility but is often difficult to diagnose. On average, it takes 8.5 years for women to be diagnosed from their first symptoms, and the current gold standard for detection is invasive surgery.

The lack of understanding about endometriosis has hidden the serious economic burden the disease places on society. The condition is estimated to cost Australia \$2.5 billion annually in direct healthcare costs, and twice this amount due to lost productivity.

The preliminary phases of the study were originally targeted for completion in 2017 but delays were experienced in obtaining ethics approval for the project. During this period the Promarker[™] technology platform was refined to provide greater levels of sensitivity for the ongoing projects.

Parasite infections: Giardia

Status update: Discovery study completed. Proof of concept study ongoing.

Proteomics International continues to collaborate with Murdoch University Veterinary School and a leading US veterinary company to create an improved diagnostic test for the parasite *Giardia*. The test under development is strain specific and could be used to test if pets infected with *Giardia* present a risk to their owners. A proof of concept study is currently underway for this project.

Giardia is one of the most common parasitic human diseases globally. About 10% of those infected have no symptoms. In 2013, there were about 280 million people worldwide with symptomatic giardiasis. In some developing countries *Giardia* is present in 30% of the population, and in the USA it is estimated that it is present in about 5% of the population.

The risk for human health is that some *Giardia* strains that affect pets can cross into humans (zoonotic), whilst others do not (host specific). Current tests cannot easily differentiate these host specific and zoonotic strains.

Asthma and chronic obstructive pulmonary disease (COPD)

Status update: Ethics approved. Discovery study pending.

The company has received ethics approval for a discovery study to identify biomarkers for asthma and chronic obstructive pulmonary disease, which cost health care systems tens of billions of dollars a year. The discovery phase will commence shortly using the PromarkerTM pipeline.

The study comes after Proteomics International joined forces with the Busselton Population Medical Research Institute in December 2017 to improve the diagnosis and treatment of lung conditions. The agreement gives Proteomics International access to the globally-recognised Busselton Health Study, one of the longest running epidemiological research programs in the world.

Mesothelioma

Status update: Discovery study completed. No novel candidates identified. Project discontinued.

Proteomics International also completed a discovery study on asbestos-related cancer mesothelioma. This research, undertaken in collaboration with the University of Western Australia Medical School, did not identify any novel biomarker candidates for the disease. The project has been discontinued.

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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. The Company's business model uses its proprietary technology platform across three integrated areas of diagnostics, drug discovery and analytical services.