



ASX Release

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Proteomics International

LABORATORIES LTD

Diagnostics R&D expanded: the Promarker™ Pipeline

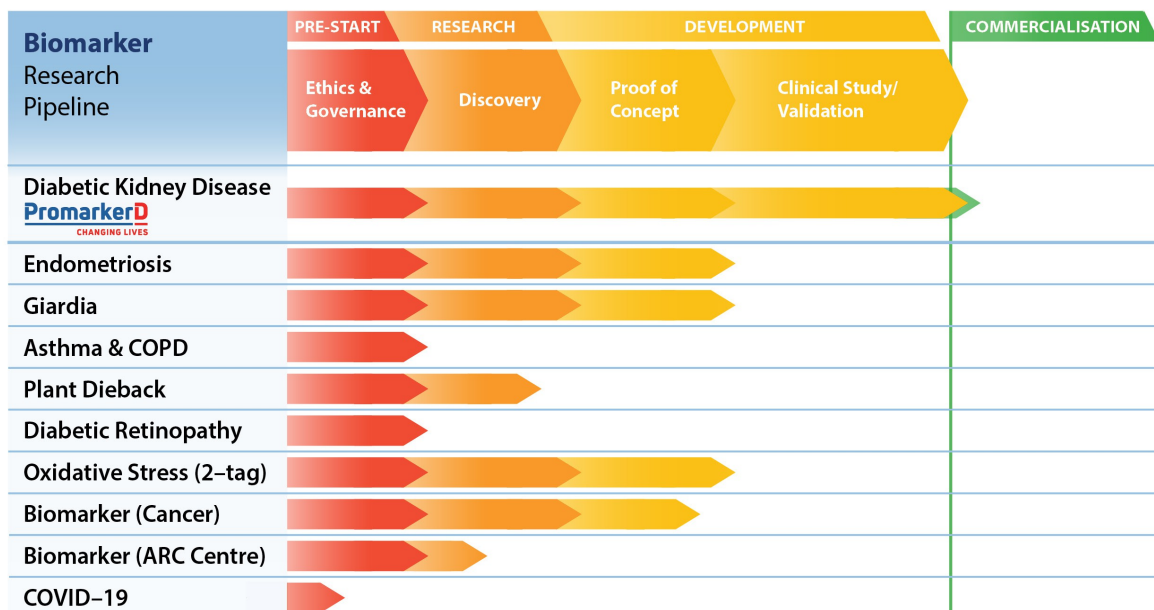
Highlights

- Biomarkers identified for Endometriosis, patent filed, successful proof of concept trial, clinical validation studies pending
- Proof of concept achieved for diagnostic to detect harmful strains of the *Giardia* parasite
- Analysis to commence into chronic lung conditions
- Advanced in-licensing and commercialisation opportunities being finalised in cancer and oxidative stress
- New biomarker programs established in diabetic retinopathy and plant dieback disease
- COVID-19 research programs initiated to develop a rapid diagnostic test for the identification of the SARS-CoV-2 virus, and to isolate biomarkers that give insights into the progression of the COVID-19 disease
- All programs are fully funded

MedTech company Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), which pioneered PromarkerD, the world's first predictive diagnostic test for diabetic kidney disease, is pleased to provide the following market update on its expanding diagnostics development pipeline.

Alongside the recent significant upgrade in the Company's analytical capability [ASX 26 November 2019], Proteomics International has been proactively vetting biomarker discovery and diagnostics development opportunities targeting new diagnostic tests for chronic diseases with significant unmet need and market opportunity across medicine, veterinary and agriculture.

DIAGNOSTICS RESEARCH AND DEVELOPMENT – THE PROMARKER™ PIPELINE



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The Promarker™ R&D pipeline and typical timeline is as follows:
Ethics & governance approval (3 months), Discovery (6 months), Proof of concept (6 months), Clinical studies/Validation (12 months)

Endometriosis

Status update: Proof of concept study completed. Clinical studies pending.

In March, Proteomics International announced it had identified and filed a patent application describing a panel of novel protein biomarkers with the potential to be developed into a simple blood test for endometriosis [ASX: 23 March].

The proof of concept study analysed 54 women across three groups: patients with endometriosis; healthy individuals and, importantly, patients with symptoms but no clinical diagnosis, to identify protein biomarkers that were statistically significant markers for disease.

Endometriosis occurs when the tissues that line the uterus spread outside of the uterine cavity and surround other organs. The debilitating disease affects one in nine Australian women, with the current gold standard for detection being a surgical procedure. Direct medical costs (outpatient and hospitalisation) associated with endometriosis in the United States surpass US\$17.3 (A\$29.3) billion annually.

Given the large unmet medical need and the only existing diagnostic tool being invasive surgery, Proteomics International believes there will be significant commercial interest in this program post successful clinical study validation.

Parasite infections: *Giardia*

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

Proteomics International continues its development of an improved diagnostic test for the parasite *Giardia* in collaboration with the Murdoch University Veterinary School and a leading US veterinary company.

Giardia is a leading cause of infectious gastroenteritis worldwide and one of the most common parasitic human diseases. The risk for human health is that some *Giardia* strains that affect pets can cross into humans (zoonotic), whilst others do not (host specific). Surveillance data suggests there are 280 million people worldwide being infected each year.

Proteomics International has identified strain specific *Giardia* targets and developed a prototype immunoassay, which is pending validation using field samples. The commercial viability of the assay will not be known until completion of this last phase, which is expected later this year.

There is a large market opportunity for Proteomics International given that current tests have low accuracy and cannot easily be used to test if pets infected with *Giardia* present a risk to their owners. A strain specific test could readily benefit the US market where according to the Centers for Disease Control and Prevention, the prevalence is an estimated 1.2 million people.

Asthma and chronic obstructive pulmonary disease (COPD)

Status update: Ethics approved. Discovery study pending.

Proteomics International 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 program was placed on hold whilst the company focused on PromarkerD clinical studies and other diagnostics projects, however, the discovery phase will commence shortly using the Promarker™ pipeline.

The study is in collaboration with the Busselton Population Medical Research Institute, which gives Proteomics International access to the globally-recognised Busselton Health Study, one of the longest running epidemiological research programs in the world.

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Plant Dieback (*Phytophthora cinnamomi*)

Status update: Discovery study ongoing.

The Company's approach to developing diagnostic tests and identifying potential drug targets is not limited to human medicine. Proteomics International has an ongoing collaboration with the Centre for Crop and Disease Management, Curtin University to target the plant pathogen *Phytophthora cinnamomi*, which is responsible for plant dieback.

The pathogen has already infected more than 1 million hectares of Western Australian bushland, and also infects premium crops such as avocados, macadamias and pineapples. *Phytophthora* attacks the roots of vegetation and inhibits them from being able to take up water and nutrients, resulting in death (termed Dieback). The estimated cost to the Australian economy is \$160 million per year for damage to natural vegetation alone.

Current investigations are focused on proteomic analysis (determining the protein maps) of the life stages of the organism and how it infects its host. This has the potential to identify weaknesses in the pathogen that could be targeted to help eradicate this disease.

Diabetic Retinopathy

Status update: Ethics approved. Discovery study pending.

Following the success of its diabetic kidney disease project, Proteomics International has signed a new collaboration agreement with The University of Western Australia to seek early markers for diabetic retinopathy.

Diabetes adversely affects the body's blood vessels leading to a range of complications including heart (cardiovascular), kidney (nephropathy), nerve (neuropathy) and eye (retinopathy) damage. Currently a third of patients with diabetes have diabetic retinopathy - vision impairment caused by damage to blood vessels at the back of the eye.

Diabetic retinopathy is the major cause of blindness in the USA, responsible for approximately 20,000 new cases each year, but finding and treating diabetic retinopathy early can reduce the risk of blindness by 95%. An early diagnosis has the ability to transform quality of life outcomes, with commensurate billion dollar socioeconomic benefits.

This collaboration will apply the Promarker platform to look for prognostic markers in the blood that can identify patients at risk of retinopathy, especially sight-threatening retinopathy. The program will again utilise the Fremantle Diabetes Study which provided the rich sample repository that led to PromarkerD.

Markers for oxidative stress - '2-tag' technology

Status update: Commercialisation discussion (Proof of concept study completed. Clinical validation pending).

Proteomics International has been in a long-term collaboration with The University of Western Australia to develop methodology that could become the next generation of medical diagnostic tests. The patented technology called "2-tag" measures the oxidative stress in a system [ASX: PIQ Prospectus 2015].

Every person has a base level of oxidative stress at all times - the human body requires oxidative stress to function. However, very high levels of oxidative stress can be dangerous and have been linked to a wide range of chronic diseases including stroke, heart attack, Parkinson's disease, and muscular dystrophy and muscle damage.

2-tag extends Proteomics International's existing technology platform to zoom further into the molecular landscape to examine not only the number and type of proteins in a sample but subtle

“decorations” on the proteins themselves.

The technology has now matured with the 2-tag test demonstrating proof of concept with several publications targeting Duchenne muscular dystrophy and new exploratory work in aquaculture and sports management.

The Company's intellectual property consists of granted patents in the USA (US 8,043,824 B2) and Australia (AU2006/001757) directed to a "Method to determine the redox {oxidation} state of proteins ('2-tag')".

Proteomics International is currently examining commercial opportunities with The University of Western Australia to exploit this innovative technology.

Biomarkers for cancer

Status update: In-licensing discussion (Proof of concept study completed. Clinical validation pending).

Proteomics International is in discussion with a pre-eminent Australian medical research institute to in-license a novel mass spectrometry based cancer diagnostic test. The Company will provide further details as this develops.

Novel disease biomarkers - ARC Centre for Personalised Therapeutics Technologies

Status update: In-licensing discussion (Ethics approved. Discovery study pending).

The Australian Research Council Centre for Personalised Therapeutics Technologies is a \$3.1 million Federally funded Industrial Transformation Training Centre (ITTC) in which Proteomics International is working alongside leading university-based researchers to apply the Promarker™ technology to Complementary Diagnostics [ASX: PIQ Annual Report 2019].

Proteomics International is in advanced discussion with other consortium members for a discovery project in an area of significant unmet medical need. The Company will provide further details as this develops.

COVID-19

Status update: Programs initiated.

Proteomics International has initiated COVID-19 research programs seeking to develop a rapid diagnostic test for the identification of the SARS-CoV-2 virus, and to isolate biomarkers that give insights into the progression of the COVID-19 disease.

These programs aim to build upon Proteomics International's unique network of commercial and research partners and the Company's experiences across diagnostics development, drug characterisation and biomarker discovery. The Company will provide further details as these programs develop.

Authorised by Dr Richard Lipscombe (Managing Director) on behalf of the Board of PIQ.

ENDS

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

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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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