Proteomics International Laboratories Ltd

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Ground-breaking Predictive Test for Diagnosis of Diabetic Kidney Disease

Life sciences company Proteomics International Laboratories (ASX: PIQ) is pleased to announce that it has produced and validated a predictive test for the diagnosis of diabetic kidney disease (DKD).

The test, called PromarkerD, is the world's first proteomics-derived predictive (prognostic) test for the diagnosis of DKD, and represents a global breakthrough in the diagnosis and treatment of the disease.

There is currently no available test for predicting the onset of DKD.

The potential global medical benefits and cost savings from PIQ's predictive test are huge. Diabetes is the fastest growing health issue in the world today and is the largest cause of kidney disease - for example, 35% of adults in the USA with diabetes have chronic kidney disease.

The ability to accurately predict the onset of DKD via a simple blood test and then provide appropriate clinical treatment to prevent the onset of the disease has the potential to save health care systems globally billions of dollars. In Australia alone, the total cost to the health system and in productivity loss attributed to diabetes is estimated at $10.3 billion annually. Of the approximately 1.7 million Australians who have chronic kidney disease, 1.5 million are not aware they have it.

The commercial benefits to PIQ in successfully commercialising the test are enormous. The potential for pharmaceutical companies to market PromarkerD to identify at-risk patient groups and then to provide drugs to manage patients more effectively could provide PIQ with substantial returns in the form of licensing fees and royalties.

Background

The test was developed using PIQ's world-leading proprietary proteomics platform to measure specific biomarkers (biological signatures) in the blood of patients with diabetes to determine the likelihood of those patients contracting DKD. Specifically, PromarkerD simultaneously measures a panel of 2-6 proteins to determine the patient's disease state.

Applying its mass spectrometry-based proteomics technology, the Company has developed a deeper understanding of DKD beyond classical pathology, by comparing the differences in the protein make-up of people with and without the disease.

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Study Results

The test was developed and validated in a $2 million clinical study of 576 patients with diabetes, followed between 2010 and 2014 in Western Australia.

The results show PromarkerD can predict:
- Which patients with diabetes will progress to have a significant decline in kidney function better than any other current known measure; and
- Which people with apparently healthy kidney function as measured by conventional tests are at risk of kidney problems.

Specifically, the clinical study, which is on-going, found that 10% of the patients had a significant and rapid decline in kidney function over the four year study period and that PromarkerD correctly predicted 67% of these individuals.

The samples in the study were cross-validated with an established antibody-based technique broadly accepted by the US Food and Drug Administration (FDA), which showed there was excellent correlation between the two methods.

PromarkerD also has a diagnostic component (in addition to its predictive application), which utilises the biomarker panel to diagnose the early onset of DKD in a patient, where current tests for kidney function fail to detect the disease.

Commercial potential

The International Diabetes Foundation estimates that 382 million people currently have diabetes worldwide and the number is expected to rise to 1 in 10 of the world's population by 2035. According to the US Centre for Disease Control, 35% of adults with diabetes have chronic kidney disease and 20% will end up with kidney failure, which can only be treated by dialysis or a kidney transplant.

Extending PIQ's clinical study findings to the larger worldwide problem suggests that 25 million individuals of the 38 million at risk of significant and rapid decline in kidney function could be identified by PromarkerD. This would represent a massive potential market for the technology owner/developer and any licensing partner(s).

PromarkerD can be commercialised simply using today's standard pathology laboratory assay systems, and, in the future, also via a specialist mass spectrometry test - which is likely to be common in next generation laboratories as technology is miniaturised.

Companies specialising in diagnostic kits may derive revenue streams and PIQ may earn royalties and/or licensing fees from a commercially available test. The global market for diagnostic kits is substantial; in the US the pathology lab industry is composed of 23,803 businesses with total annual revenue of US$55 billion. Australia has 278 businesses generating $3 billion in total annual revenue.

Next steps

The Company is attending BIO 2015, the world's largest biotechnology conference in Philadelphia, USA, next week for discussions with major pharmaceutical companies. PIQ will also continue to engage with global industry players for partnering and licensing opportunities to commercialise PromarkerD as a ground-breaking predictive test for the diagnosis of diabetic kidney disease.

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About Proteomics International Laboratories Ltd (PILL)

PILL is an ASX listed (ASX: PIQ) life science company focused on the area of proteomics – the industrial scale study of the structure and function of proteins. Proteomics is an integral part of the biotechnology and life sciences industries and plays a key role in understanding disease and biological systems. It represents a massive global market estimated to be worth $20.8 billion by 2018.

PILL is an established, revenue generating business and is recognised as a global leader in its field. It received the world's first ISO 17025 laboratory accreditation for proteomics services, and operates from state-of-the art facilities at the Harry Perkins Institute of Medical Research in Perth, Western Australia. The Company's business model uses its proprietary technology platform which operates across three synergistic proteomics-based business units in massive growth markets:

1. Analytical services: Specialist contract research, analytical testing and consultancy - fee for service model.

2. Diagnostics: Biomarkers of diseases and personalised medicine - focus on diabetic kidney disease and Alzheimer's disease. The biomarkers market is estimated to double in size to $40.8 billion by 2018.

3. Drug discovery: Therapeutic drug discovery with a focus on painkillers and antibiotics. The peptide therapeutics market is currently estimated to be worth $17 billion.

What is proteomics?

Proteomics is the industrial scale study of the structure and function of proteins. The protein make-up in our bodies differs from cell to cell and changes considerably over time. For example, a cancerous cell will have significantly different proteins to a healthy cell. Understanding proteomics can speed up diagnosis and the identification of drugs that can be used to treat diseases. As recently as 15 years ago, identifying a single protein (a process called sequencing) took around 24 hours, and required comparatively large amounts of highly purified sample. Today, PILL can identify a protein in 10 seconds and complex mixtures can be quickly and accurately analysed. This drives the Company's business model across its three areas of operation.

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