



Proteomics International

LABORATORIES LTD

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Proteomics International to patent biomarkers for diagnosis of endometriosis

- **Newly identified biomarkers via the Promarker™ platform provide breakthrough for Proteomics International in the effort to create a world-first test for endometriosis**
- **Proof of concept study performed on 54 women returned statistically significant results**
- **Patent application filed for the invention, which uses protein biomarkers taken via a standard blood sample as a novel test for diagnosing endometriosis**
- **Debilitating condition affects 1 in 9 women and costs Australia over AU\$10 billion a year**
- **Diagnosis of endometriosis typically takes 7 to 12 years due to the lack of a diagnostic tool beyond invasive surgery**
- **Proteomics International looking to partner with organisations with access to patient samples ahead of a large clinical study, which is anticipated to provide the basis for commercialisation**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) announces it has identified protein ‘fingerprints’ in the blood that could be used to test for endometriosis.

The ‘fingerprints’—known as biomarkers—have potential to be developed into a simple blood test for the painful condition. If successful, it would be the world’s first non-invasive test for endometriosis.

In isolating the biomarkers, Proteomics International scientists compared patients diagnosed with endometriosis (via a laparoscopy) against two control groups; healthy individuals and, importantly, patients with symptoms but no clinical diagnosis.

“Our proof-of-concept study analysed 54 women across the three groups,” said Proteomics International managing director Dr Richard Lipscombe. “The study was performed on two independent cohorts, with the protein biomarkers being statistically significant markers for disease in both.”

Dr Lipscombe said the next stage is to validate the biomarker panel in a large clinical study. “We’re looking to partner with organisations who have access to a large number of high-quality samples from endometriosis sufferers,” he said. “And we’re hoping to collaborate with key bodies and opinion leaders from around Australia.”

Successful validation of the biomarker panel in a larger trial is anticipated to form the basis of commercialisation. Proteomics International will endeavour to commercialise the test through a licensing model, utilising its learnings and industry contacts that have developed throughout the commercialisation of its predictive test for diabetic kidney disease, PromarkerD.

Proteomics International has also submitted a patent application following extensive analysis of the

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biomarkers. The patent describes a panel of novel protein biomarkers with the potential to diagnose endometriosis using a simple blood test.

Endometriosis is a debilitating disease that affects one in nine Australian women. There is currently no simple way to test for the condition, with the current gold standard for detection being an invasive laparoscopy, a surgical procedure where a camera is inserted into the pelvis through a small cut in the abdominal wall.

The average cost for a woman with endometriosis both personally and for society is approximately A\$30,000 a year, costing Australia over A\$10 billion every year¹, whilst direct medical costs (outpatient and hospitalisation) associated with endometriosis in the United States surpass US\$17.3 (A\$29.3) billion annually².

On average, it takes women 7 to 12 years to be diagnosed. Experts says endometriosis symptoms often start during the teenage years, but because it's hard to diagnose, girls can struggle with unexplained pain through high school, tertiary education and the early years of their careers. Dr Lipscombe said, "If we can create a simple blood test that can be ordered by a GP, it could save women years of suffering."

The biomarkers were isolated using a variation on Proteomics International's Promarker™ workflow and took advantage of the increased analytical sensitivity of the Company's recently upgraded instruments [ASX 26 November 2019]. The same technology was used in the creation of the world's first blood test for diabetic kidney disease, known as PromarkerD. That test is currently in commercial roll out.

With experience gained from the development of PromarkerD, Proteomics International is now undertaking an analytical validation of the biomarkers to prove their robustness under a range of sample preparation and analysis techniques. "We're seeking to make a blood test for endometriosis available as soon as possible, to stop patients having to go through years of delayed diagnosis," Dr Lipscombe said.

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

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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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¹ <https://doi.org/10.1371/journal.pone.0223316>

² <https://doi.org/10.1007/s12325-018-0667-3>