



Proteomics International
LABORATORIES LTD

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Promarker pipeline - Endometriosis update Diagnostic readout positive: Study expanded

- **Panel of statistically significant biomarkers for endometriosis clinically validated using samples from 857 patients**
- **Research could lead to the world's first non-invasive test for endometriosis**
- **Study in collaboration with the Royal Women's Hospital and University of Melbourne will now be expanded to include St John of God Health Care**
- **Results will be presented at the Fertility Society of Australia and New Zealand Annual Conference (FSANZ 2022), being held 30 July - 2 August 2022**
- **Endometriosis affects one in nine women and currently diagnosis typically takes an average of 7.5 years**

Medical technology company Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) is pleased to announce it has completed the initial analysis of its endometriosis clinical validation study aimed at diagnosing the gynaecological condition using a simple blood test. Preliminary results show several plasma proteins are statistically significant biomarkers for endometriosis.

Endometriosis affects one in nine women and costs Australia \$9.7 billion each year¹. At the moment, there is no simple way to test for the condition, which often causes pain and infertility.

The current gold standard for detection is an invasive laparoscopy, a surgical procedure where a camera is inserted into the pelvis through a small cut in the abdominal wall. On average, it takes women 7.5 years to be diagnosed².

The Promarker endometriosis validation study is a collaboration with the University of Melbourne and the Royal Women's Hospital [ASX: 4 August 2021] that aims to test the effectiveness of a panel of candidate biomarkers discovered by Proteomics International in a pilot study [ASX: 23 March 2020].

In clinically validating the biomarkers Proteomics International's scientists compared 857 samples across three groups: women who had been diagnosed with endometriosis through a laparoscopy (N=468), and two control groups; healthy individuals (N=147) and, importantly, patients with symptoms but no clinical diagnosis (N=242).

The clinical samples were collected over several years from patients who attended a Royal Women's Hospital pelvic pain clinic, and include samples from women with different grades of endometriosis

¹ www.endometriosisaustralia.org

² www.endometriosis-uk.org

and also patients with various gynaecological symptoms but no endometriosis. The healthy control samples were recently collected from volunteers recruited by the Company.

The study was successful in identifying a panel of several biomarkers that were statistically significant ($P < 0.05$) in the large clinical cohort at differentiating samples from the endometriosis positive (by laparoscopy) group against those with symptoms but no clinical diagnosis.

The results will be presented at the Fertility Society of Australia and New Zealand Annual Conference (FSANZ 2022), being held 30 July - 2 August in Sydney, NSW.

The next phase of analysis will use the validated biomarkers to build a diagnostic model, as was performed for PromarkerD, the Company's novel diagnostic test for diabetic kidney disease (DKD). This process of statistical modelling will determine the accuracy (sensitivity and specificity) of the new test and will take approximately one month. These results will also be presented at FSANZ 2022. The Company will then seek to confirm the clinical performance of the new test in an independent patient cohort.

To support this independent validation, Proteomics International also announces an additional collaboration with St John of God Health Care. The Company has signed a material transfer agreement to access approximately 250 clinical samples from the St John of God Subiaco Hospital Gynaecological Cancer Research Group that were obtained from patients with either clinically-confirmed endometriosis or other benign (non-cancerous) conditions.

Proteomics International managing director Dr Richard Lipscombe said, *"We are excited to have passed this significant milestone on our way to developing what we hope will be the world's first non-invasive test for endometriosis. The clinical validation results are the foundation for turning the biomarkers into a new diagnostic test for endometriosis, and then the new collaboration with St John of God Health Care enables us to take another critical step in the commercialisation path by confirming the performance of our novel test in an external patient group."*

In interpreting these initial results, it is important to recognise that endometriosis is a highly complex condition with a broad spectrum of clinical indications. Consequently, endometriosis is not necessarily a simple positive versus negative test, and further work may be required to detect these subtle variations.

Dr Lipscombe said, *"The statistical modelling and subsequent independent study will prove if we have a viable, novel, non-invasive test for endometriosis, and we believe this program will garner significant interest, both commercially and in the clinic"*.

Proteomics International has already developed PromarkerD, the world's first predictive diagnostic test for DKD. The Company's Promarker™ pipeline contains further research programs targeting asthma and COPD, oesophageal cancer and more.

Authorised by the Board of Proteomics International Laboratories Ltd (ASX:PIQ).

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About the Promarker™ Platform

Proteomics International's proprietary technology identifies the proteins that give insight into disease. The human body contains an estimated 20,000 genes coding for proteins. However, there are multiple levels of regulation and modification between reading a gene and producing the final protein product. As a result, over 200,000 proteins are predicted to co-exist in the human body, interacting in a complex network. Proteomics International uses its Promarker™ platform to identify biomarkers - protein "fingerprints" associated with disease. These biomarkers can be used to diagnose medical conditions, or predict whether a person will develop a disease in the future [For further details see the PIQ Annual Report 2020 - Technology Snapshot].

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 | W: www.proteomicsinternational.com

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. Proteomics International's mission is to improve the quality of lives by the creation and application of innovative tools that enable the improved treatment of disease.

For further information please contact:

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

Dirk van Dissel
Investor Relations & Corporate Advisor
Candour Advisory
T: +61 408 326 367
E: dirk@candouradvisory.com.au

Kyle Moss
Corporate Advisor
Euroz Hartleys
T: +61 8 9488 1400
E: kmoss@eurozhartleys.com