

## ASX ANNOUNCEMENT

### Analytica receives FDA Over-the-Counter clearance for PeriCoach®

**12 July 2016; Brisbane, Australia** – Analytica Ltd (ASX: ALT) is pleased to announce that the US Food and Drug Administration (FDA) has granted the company over-the-counter (OTC) clearance for the PeriCoach system, previously available in the US by prescription only.

The PeriCoach is a unique medical device that assists women to exercise their pelvic floor muscles in order to reduce or eliminate Stress Urinary Incontinence, a condition that affects 1 in 3 women.

“Women can use pelvic floor exercises or “Kegels” to reduce or eliminate urinary incontinence symptoms, and with PeriCoach now available over the counter, home training just got a lot more convenient,” said Leslie Rickey, MPH, MD, Associate Professor of Urology and of Obstetrics, Gynaecology and Reproductive Sciences and Fellowship Director of Female Pelvic Medicine and Reconstructive Surgery, Yale School of Medicine.

“It is critical that women put their trust in new technology for pelvic floor muscle training that has been medically tested and FDA-cleared, as these products have an internal component and are designed to treat a real medical condition.” said Dr Rickey.

Urinary incontinence (UI) affects approximately 25 million women in the United States. The National Association for Continence reported that women wait up to six years before talking with a clinician about their UI, as they are too embarrassed to discuss the issue or believe it is a normal condition.

The US market for incontinence pads is worth \$5 billion a year and whilst diapers and pads are a common option for women, they only address the symptom of leaking and not the underlying cause of the condition. The American College of Physicians recommend pelvic floor exercises as the first line treatment option for conservative management of UI as they have been proven to be effective if performed consistently and properly.

Analytica CEO, Geoff Daly said “This is a terrific achievement for Analytica which opens up a significant market opportunity within the United States, and also positions us attractively for a potential licensing partner. Achieving OTC clearance in such a short time means the device is more easily accessible by women in the US who will no longer need a referral from their health professional to purchase the product. This will help to raise awareness amongst physical therapists and health care professionals who remain an important channel.”

“Our regulatory clearances provide assurance to customers and clinicians that the product has been designed, developed, tested and manufactured to internationally recognised medical device standards.” said Mr Daly.

Ms Megan Henken, Analytica’s VP Global Marketing said: “PeriCoach has a clear point of difference as an e-health treatment system supported by the clinical community, and a tool that enables women to address incontinence issues in the comfort of their own homes. With over the counter regulatory clearance, women in the US can now confidently purchase the device without a referral from their clinician, in line with the regulatory clearances we have already achieved in Australia and the UK.”



For more information, please contact: [investorrelations@analyticamedical.com](mailto:investorrelations@analyticamedical.com)

For more information about the PeriCoach System, visit: [www.PeriCoach.com](http://www.PeriCoach.com)

For more information about Analytica, visit [www.AnalyticaMedical.com](http://www.AnalyticaMedical.com)

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### About Analytica Limited

Analytica's lead product is the PeriCoach® System – an e-health treatment system for women who suffer Stress Urinary Incontinence. This affects 1 in 3 women worldwide and is mostly caused by trauma to the pelvic floor muscles as a result of pregnancy, childbirth and menopause.

PeriCoach comprises a device, web portal and smartphone app. The device evaluates activity in pelvic floor muscles. This information is transmitted to a smartphone app and can be loaded to a cloud database where physicians can monitor patient progress via web portal. This novel system enables physicians to remotely determine if a woman is performing her pelvic floor exercises and if these are improving her condition.

PeriCoach has regulatory clearance in Australia, and has CE mark and USFDA 510(k) clearance. The product is available for sale in Australia and New Zealand, UK and Ireland, and in the USA.

