

16 April 2015

## ASX ANNOUNCEMENT

### PERICOACH CLINICAL TRIAL RECRUITMENT COMMENCES

- **Analytica commences patient recruitment for a Clinical Trial for PeriCoach®, a personal pelvic floor muscle training system used for treatment of urinary incontinence and female sexual dysfunction..**

BRISBANE, Australia – Analytica (ASX: ALT) is pleased to announce the commencement of patient recruitment for the first prospective multi-centre clinical trial of The PeriCoach® System, a personalised device, web portal and smartphone app that provides real-time biofeedback for pelvic floor muscle exercises.

These clinical trials are not required for registration or sales clearance. The value of PFME is already well documented and widely accepted. The trials provide Analytica with:

- a foundation for market differentiation.
- clinician confidence and medical bona fides.
- Peri-Coach-specific efficacy information for reimbursement studies.

Weak pelvic floor muscles can contribute to bladder leakage and sexual dysfunction. Pelvic floor muscle exercises (PFME) are recommended by the prestigious American College of Physicians as first-line non-pharmacological treatment for urinary incontinence. The PeriCoach system provides real-time biofeedback to enhance the performance and effectiveness of performing PFME.

The company's marketing strategy is to build confidence for women and clinicians that the PeriCoach is the most trustworthy and rewarding investment for effective PFME. The elements to achieve that goal are, good science, testing, feedback, testing, registration as a medical device (not as a toy or gimmick), testimonials by happy women and rigorous independent testing across a large population.

The PeriCoach system's patented technology is a result of five years research and testing to international standards. Usability trials and the expanding collection of testimonials lends further support for the effectiveness of the PeriCoach.

The PeriCoach system has achieved registration as a medical device with the TGA (Australia), CE-marking for Europe, and FDA clearance (United States) by exceeding the onerous and costly regulatory requirements put in place to ensure patient safety.

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The value of the trials is to provide an opportunity for independent validation of the product efficacy. But they do have significant challenges. To achieve clinical trial registration, a strict protocol requires extensive design by specialist clinicians. Independent personnel are engaged to build and conduct the clinical trial. Hospital Ethics committee examine and determine the risk/benefit of the trial. After a large investment in time and funds, clearing all these hurdles the trial can commence recruiting participants. Well designed and executed clinical trials can provide evidence that is accepted globally.

The PeriCoach trial is investigating urinary incontinence and has a secondary endpoint investigating quality of life improvements, including sexual function. 100 patients will be recruited at 4 Australian sites over the coming months, with each patient monitored over 20 weeks.

Dr Ailsa Wilson Edwards, MD, urological surgeon at Continence Matters, Adelaide, will serve as lead investigator.

A well-credentialed and effectively run clinical trial not only provides women and clinician confidence, it provides the data for health economic studies to determine the value of the PeriCoach system for third parties such as health reimburses and insurers.

The PeriCoach recently received 510(k) clearance by the US Food and Drug Administration allowing marketing into the US where it is a prescription-only device. The product will be launched and available for sale in late Spring (USA) 2015. It is also cleared for sale and available to the public in Australia without prescription.

Clinician engagement is a key part of the global marketing strategy. Analytica recently demonstrated the PeriCoach system at the Royal College of Obstetricians and Gynaecologists (RCOG) World Congress at the Brisbane Convention Centre. Analytica is currently presenting two scientific posters at the Simon Foundation "Innovating for Continence" meeting in Chicago, Illinois, USA later this week.

"We are excited to take this important next step in our continuing efforts to help the clinical community and women reduce or eliminate urinary incontinence and other pelvic floor disorders such as sexual dysfunction." said Geoff Daly, Analytica CEO. "Effective pelvic floor muscle exercises are a critical component of any comprehensive treatment program for urinary incontinence. Our goal with this trial is to partner with clinical centres and the professional community to understand how PeriCoach help improve the compliance and effectiveness of these proven exercises."

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 PeriCloud 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 clearance. Product launches are anticipated in Europe and the US in 2015. The US market for incontinence pads is \$5 billion pa. It is projected that by 2030, 5.6 million women in Australia will suffer urinary incontinence. The product is pending USFDA 510(k) clearance in the USA.*



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