



ANALYTICA LTD - ABN 12 006 464 866

## **ASX ANNOUNCEMENT**

## Change in PeriCoach Manufacturer for US Market

## Reduction in Cost of Goods.

**23 March 2018**. Analytica Ltd (ASX:ALT) is selecting a new manufacturer for its PeriCoach product in the US market following the decision by the product's previous manufacturer of record to withdraw USFDA registration.

Analytica is also bringing forward plans to expedite the next stage of development, which focuses on reduction of cost of production. This reduction of cost of production will be advantageous in negotiations with multinationals. Analytica is currently reviewing several suitable alternative manufacturers who bring additional capabilities for the product development roadmap as well as meet the necessary regulatory requirements.

The PeriCoach is a class II medical device in the US and requires a US Quality System Regulation (21 CFR 820) compliant manufacturing facility to be registered with the USFDA.

The previous manufacturer is repositioning itself towards high-volume, established clients and Analytica, as a product development company, is no longer an appropriate fit. The next stage of PeriCoach commercialisation, required the assistance of the manufacturer, which they have indicated, they are not able to provide.

As per USFDA requirements, Analytica has suspended supply of the PeriCoach in the US only until a new manufacturer can be registered. Suspension of US sales, which are modest, as data collection is the objective, is preferable now than later in the year.

This decision by the manufacturer does not affect the company's ability to supply outside the US and is not expected to make a significant difference in the company's financial position, or ability to negotiate a deal for licensing or sale of the PeriCoach or Company. Analytica owns all PeriCoach production tooling and jigs and can transfer to a new manufacturer as required.

Analytica Chairman Dr Michael Monsour said "This decision by our previous manufacturer will require a change in our operating priorities for a few months. It also provides a significant opportunity to implement product and production improvements that have been waiting in the wings and enhance the value of any future transaction. Upgrading the designs and processes, and reductions in cost of goods will be valuable to a potential deal partner."

For more information, please contact: investorrelations@analyticamedical.com
For more information about the PeriCoach System, visit: www.PeriCoach.com
For more information about Analytica, visit 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. Strengthening of the pelvic floor muscles can also potentially improve sexual sensation or satisfaction and orgasm potential in some women.

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