

ASX ANNOUNCEMENT

Analytica Announces Expansion of PeriCoach® Pelvic Health Solution into China

30th March 2021, Brisbane, Australia

- PeriCoach will be distributed through extensive network of postpartum care centres, hospitals, pharmacy chains, and online platforms serviced by the JV partners.
- Agreement builds upon existing Middle East distribution partnership in 10 countries to facilitate growth and manufacturing of PeriCoach in international markets.
- Clinical trial confirms unsupervised PeriCoach treatment is on par with in-clinic pelvic floor physical therapy for treating stress urinary incontinence, at much lower cost overall.
- PeriCoach provides cost-effective solution to improve quality of life and ease burden of care in postpartum as well as aging populations and eliminating the daily cost of diapers.

Analytica Limited (ASX:ALT), the Australian manufacturer of the PeriCoach pelvic floor exercise system for the treatment of stress urinary incontinence, has entered into a joint venture (JV) agreement to manufacture, distribute and market the system in China, Macau, Hong Kong and Taiwan. The JV partners with Hebei NACOL Bio-Technology Co., Ltd (**Nacol**) and Shijiazhuang Biosphere Pty Ltd (**Biosphere**), Peoples Republic China (PRC) companies based in Hebei Province.

Nacol key shareholders includes two highly experienced Chinese medical manufacturing and distribution companies, Hebei Aineng Biological Technology Co., Ltd and Shijiazhuang YST Medical Supplies Co. Ltd.

The JV will register PeriCoach with the Chinese Food and Drug Administration (CFDA) as a class II medical device. With CFDA clearance, PeriCoach can become a prescription treatment, initially covering the hospital network in the North China area.

Expansion into China will support the distribution of PeriCoach to both the rapidly growing postpartum rehabilitation market and the early-stage preventative senior market, as one in three women worldwide suffer from stress urinary incontinence. The agreement furthers Analytica's strategy to bring PeriCoach into global markets, building upon growth in the Middle East with partner Motion Egypt LLC, and pursuit of other partners in North America, Europe and Southeast Asia outside of China.

PeriCoach is comprised of a medical device, smartphone app and the PeriVault, the largest pelvic floor muscle exercise database in the world. PeriCoach includes biofeedback technique guidance technology that helps women correctly perform pelvic floor exercises, also known as "Kegel" exercises, while the device and app are being used. Real-world data from PeriCoach patients¹ shows that majority of women do not know how to engage these hidden muscles when they first use the device. PeriCoach technique guidance means "Kegels" can be done correctly and confidently by any woman in the privacy of her own home. PeriCoach is the only device which actually measures the muscle strength in the pelvic floor.

A recent independent, peer-reviewed, randomized controlled clinical trial^{2,3} performed at the University of New Mexico and published in the *Journal of Female Pelvic Medicine & Reconstructive Surgery* concluded that the PeriCoach biofeedback system, with no formal instruction, is non-inferior and on par with in-clinic pelvic floor physical therapy in a pelvic floor centre of excellence, making this system



the most cost-effective⁴ form of treatment for stress and mixed urinary incontinence..

Currently manufactured in Australia, the new PeriCoach manufacturing line for the Chinese market only is located in the Shijiazhuang National New and High Technology Development Zone and will be listed as one of the major projects in the free trade zone and high technology zone.

PeriCoach will be distributed through the existing extensive network of hospitals and postpartum organisations serviced by the JV partners. The JV partners have collaborated with a leading postpartum care service platform in China with coverage of 100 cities and more than 30,000 clinical professionals.

In China, 15 million babies are born each year.⁵ With the rapid development of the modern economy, the postpartum rehabilitation industry has grown to 3.95bn yuan pa (US\$608M) in 2018, with a compound annual growth rate of 43.9%.⁶

Furthermore, China, as with Western countries, has an aging population among which 31% of older women experience urinary incontinence, but only 25% of those currently seek medical assistance.⁷ The JV sees a large public health opportunity for conservative treatment of incontinence in women aged 50-70 years, reducing the quality-of-life impact along with the longer-term economic burden of aged-care.

The CEO of Aineng, Dr LanJu Xu, will lead the JV and comments: "We have strong confidence in Analytica's R&D capabilities and do believe that Analytica and NACOL can take advantage of each parties' strengths from this Joint Venture and achieve a win-win situation. Bringing together Analytica's leading technology and NACOL's extensive industry resources in China, we are looking forward to witnessing PeriCoach enter this huge market."

Mr Xu has a strong background in medical devices and materials, including a track record of 17 class II medical device approvals and completed clinical trials of two class III medical devices. He is also the Team Lead for Key Research & Development (R&D) Program of the Ministry of Science and Technology in China, which is operated by four leading universities and one of the top three hospitals in China. Additionally, Mr Xu is the lead of the medical material R&D Center in Nankai University.

Analytica Chairman, Dr Michael Monsour, comments: "Entering the China market with such nimble, experienced operators is a major milestone for Analytica. China is leading the world in recognising the need for effective postpartum care and is facing the challenge of caring for its large aging population by using the PeriCoach system to assist women with managing incontinence. PeriCoach is a proven cost-effective solution that will dramatically improve quality of life and burden of care for women including the use of costly diapers. We look forward to the continued exploration of our strategic options to expand the availability of PeriCoach globally."

Analytica has recently moved its Australian manufacturing operations and is looking to online sales in the US, UK/Ireland, Australia and New Zealand in the near future. PeriCoach has USFDA 510(k) clearance, Australian ARTG registration, and CE-marking.

The joint venture interests are Hebei NACOL (65%), Analytica (20%) and Biosphere (15%). The joint venture agreement contains mechanisms to assist Analytica maintain its 20% shareholding until Hebei NACOL has made a total share contribution of RMB 10 million cash.

Analytica's shareholding in the joint venture company confers on it voting rights and rights to share in any surplus on liquidation. As Analytica is entitled to a 15% royalty income from joint venture sales, it is not entitled to share further in the joint venture dividends, which will be distributed to the other joint venture parties in



proportion to their shareholdings.

Under the joint venture, Nacol is responsible for the registration of the joint venture company, obtaining the necessary PRC regulatory approvals (including a business license and product approval licence), manufacturing, distribution and marketing of the PeriCoach®.

It is also responsible for providing all the necessary funding for the future development of PeriCoach® (including by way of shareholder loans of not less than five years maturity at interest rates in the PRC) and ensuring that products manufactured by the joint venture company meet ISO standards.

Analytica will retain ownership of the PeriCoach® intellectual property and be entitled to continue to develop it and exploit it independently outside the agreed territories. Any PRC product approvals (for example medical device registration or medical device filing) will be held in the name of Analytica. Joint improvements to the intellectual property will be jointly owned by the joint venture company and Analytica.

Analytica will have 2 board seats out of a total of 5 on the joint venture company. The chairman will be a Nacol director nominee. Shareholder decisions will be made by majority vote except for a number of reserved matters which require the approval of Analytica and Nacol as well as a majority of shareholders holding at least two thirds of the registered capital of the joint venture company. These include decisions relating to the issue of new shares, distributions of net profit, approval of the annual business plan and budget, material capital expenditure and KPI setting each year.

The technology licence agreement contains commercial provisions which are commonly found in manufacturing and distribution licenses relating to the protection and use of licensed intellectual property for the manufacture, marketing and distribution of products manufactured under licence; compliance with quality assurance standards; reporting of manufacturing costs, production records, historical and sales forecasts; setting KPIs for marketing spend and sales targets each contract year; the auditing of sales to verify royalties; and non-compete and non-solicitation obligations by the joint venture parties.

Authorised for release by the Board.

Dr Michael Monsour

Chairman

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

References

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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 for urinary incontinence in Australia and has CE mark and USFDA 510(k) clearance.

PeriCoach also has clearance in Australia, and CE Marking in Europe for the treatment of pelvic organ prolapse, a condition that affects up to 1 in 5 women during their lifetime.