



ANALYTICA LTD - ABN 12 006 464 866

#### ASX ANNOUNCEMENT

#### Annual General Meeting Chairman's Address and CEO Presentation

**30**<sup>th</sup> **November 2017:** Analytica Ltd (ASX: ALT) presents the Chairman's address and CEO presentation.

Key messages:

#### Commitment to shareholders at 2016 AGM

- Build best in class PeriCoach V3
- Prove it works
- Shore up share registry to protect shareholders
- Ensure cash resources to protect company
- Restructure board to skill up for commercialisation
- Appoint Investment Banker to pursue commercialisation opportunities

#### Analytica's Achievements

- PeriCoach V3 released May 2017 an evolution not an upgrade.
  - Ability to assist technique more than 50% of women can't perform pelvic floor exercises correctly
  - Motivation and encouragement greater app support.
  - Evidence-based training programme.
- Clinical trial data published exceptional quality of life and sexual function result.
- Developed analysis tools for V3 and 8-week challenge data greater insights into pelvic floor treatment.
- Regulatory approvals for pelvic organ prolapse underway.
- Successful capital raising with further option exercise income due 2018.
- Board appointments with deal experience and networks.
- Build comprehensive evidence and support data to facilitate commercialisation.
- Appointment of investment banker in September 2017.



#### Analytica Chairman's Address to Shareholders at the Annual General Meeting

#### 30 November 2017

Good morning Ladies and Gentlemen and welcome to the 2017 AGM of your company, Analytica.

12 months ago, at the last Analytica AGM I made the promise that management and your board would work tirelessly to put Analytica in a position so that by the end of the third quarter 2017 we would be ready to do a deal with a major multinational for both the PeriCoach and AutoStart Burette and possibly the whole company.

To reach the stage where the company is deal ready, Analytica had to achieve the following milestones:

- 1. Develop and get to the market the PeriCoach V3
- 2. Collect evidence to prove the PeriCoach V3 works and works far better than the PeriCoach V2 or any other device on the market.
- 3. Shore up our share registry so that in the event of a hostile takeover we could always control the deal.
- 4. Fix up our balance sheet so that a licencing partner could not hang us out to dry before doing a deal on their terms.
- 5. Restructure our board to give us the networks and skills to partner with the right Investment Bank to achieve the aim of a deal with one or more multinationals.
- 6. Compile the resources needed to assist a commercialisation partner to appreciate the capability of both the PeriCoach and the AutoStart Burette.
- 7. Appoint an Investment Banker preferably from the US to run the commercialisation of both the PeriCoach and the AutoStart Burette.

At our last AGM, I advised our shareholders that it was Analytica's aim to reach all these milestones by the end of the third quarter this year.

Today Ladies and Gentlemen I wish to announce that your company has achieved these milestones.

I will now go through each of these 7 critical steps in more detail.

#### PeriCoach V3

At our last AGM I told the meeting the following and I quote:

"Our engineering department has been busy developing the next generation of the PeriCoach, what we call the PeriCoach Version 3.

Whereas the PeriCoach V2 is a biofeedback device measuring the force of the pelvic floor muscles, the PeriCoach V3 is able to analyse each and every pelvic floor contraction, making sure that the muscles contract correctly.

In other words, the PeriCoach V3 is a digitalized pelvic floor physiotherapist."



On May 1 this year, Analytica announced to the market that we had achieved this goal of developing the PeriCoach V3 and that we had released the first production units of the PeriCoach V3 to the market. The aim of this release was to collect data and evidence to prove how effective the PeriCoach V3 is.

Let me first say, that the PeriCoach V3 is like no other perineometer on the market. The V3 directly addresses the major handicaps of effective Kegel exercise. Despite being told that Kegel exercises work many give up as they don't know if they are doing them correctly. This is understandable as the muscles are hidden and there is much misinformation amongst women trying to do them.

The PeriCoach V2 measures the force of the pelvic floor muscles which enable real time biofeedback of the force of these muscles to the patient and clinicians.

However, the PeriCoach V3 is much more than this. The V3 analyses each and every pelvic floor contraction and is then able to tell the woman whether her technique is correct or not. This allows the woman to learn to correct and improve her technique which directly leads to an improvement in her pelvic floor muscles.

Women have busy lives and there are many factors that impact pelvic floor health. Analytica's investment in data collection has simplified and personalise their exercise program.

Women now have to spend less than 5 minutes a day to notice effective improvement in their pelvic floor strength, urinary incontinence and sexual health.

The real power of the data is unseen. The clever mathematics and algorithms analysing the movement of the pelvic floor enables Analytica to get new insights into the workings of the pelvic floor muscles.

In essence, the PeriCoach V3 is an "in house" personal digitalised pelvic floor physiotherapist.

#### Real World trial of the V3

On May 4 2017, we announced that

"Analytica has released a scientifically-developed, structured exercise programme for the PeriCoach system App to drive motivation and exercise compliance."

At the same time, we commenced an 8-week challenge for patients using the PeriCoach V3.

The aim was to collect data on women using the PeriCoach V3 in the real world. Data in the 21<sup>st</sup> century is the new currency and has significant commercial value in developing personalised treatment programs.

We are collecting data on the improvement in muscle strength, muscle endurance, incontinence improvement, quality of life and sexual health on women using the PeriCoach V3.

This real-world trial has already collected a massive amount of data.

Analytica now has the world's largest data base on pelvic floor muscles.

This data collection is ongoing.

This evidence is pivotal in distinguishing the PeriCoach V3 from other competitors who lack clinical evidence and FDA registration for stress urinary incontinence and sexual function.

It is to be noted that the multinational medical device companies have told us how important clinical evidence is to them.

We intend to use this data to maximise the value of any potential sale or licence agreement for the



PeriCoach V3.

Analytica is also working on getting the PeriCoach V3 approved for use in pelvic organ prolapse.

Once obtained, this will open up the potential market for the PeriCoach V3 and of course increase the value of the PeriCoach V3 for any potential multinational purchaser or licensee.

After TGA, CE and FDA approval, we will be able to make claims that the PeriCoach V3 can be used to treat not only stress urinary incontinence and female sexual dysfunction but also uterine prolapse and rectal prolapse.

The pelvic organ prolapse market is a massive market equal to the size of the stress urinary incontinence market.

#### Share Registry.

When we first had discussion about engaging with New York based investment banks we were strongly advised that before doing so, we needed to make sure that Analytica was not vulnerable to a hostile takeover at a low-ball figure. With our current share register, we believe that we are now in a position to control any deal in the case of a hostile takeover.

#### Balance Sheet.

Once again, the early advice we got was not to enter negotiation with any multinational until we were sure that Analytica had enough cash in the bank so that we could not be hung out to dry during any negotiations.

On the 18<sup>th</sup> September, Analytica announced to the market that we were doing a rights issue to improve our balance sheet. This capital raising was extremely successful having raised total of \$1,349,000. It is to be noted that the major shareholders including myself and Dr Peter Corr took up their full entitlement in this offering.

#### Board

Early in 2017 it became evident that Analytica needed to attract to the board people skilled in dealing with New York Investment Bankers and large multinationals.

On the 23 May this year I welcomed to Analytica's board Dr Peter Corr.

It would be fair to say that many Australian companies are envious of Analytica having attracted to our board the likes of Dr Thomas Lönngren from Sweden and Peter Corr from the USA. Dr Thomas Lönngren as the ex-head of the EMA is well known in big Pharma and medical device world.

Peter Corr is also well known in Big Pharma and New York based Investment Banking circles. Peter has a long history of doing mega deals with multinationals in the US, Europe and Asia.

#### Data Room

I will now move onto the Data room and why we have spent so much time and effort getting this right.

A commercialisation partner won't just want our word for it, that we have excellent products.

They understandably want to know, what they are buying.

For the last 8 months, our team have compiled the information needed to support the credentials of the products.



Credit to our whole team, this is not an insignificant effort.

#### Investment Banks.

On the 27 September Analytica announced that we had engaged a US corporate advisory firm.

Then on November 6th we notified the market that

"Analytica is pleased to announce that New York based Investment Bank, Navigant Capital Advisors LLC has been retained by Analytica to run the process for the sale of PeriCoach, AutoStart Burette and the possible sale of the company."

Navigant is a major US based Investment Bank with over 5,500 employees in over 50 offices in the US alone.

Navigant's job over the coming months is to enact a sale or global licence deal for both the PeriCoach and the AutoStart Burette and or possibly the sale of the whole company.

Analytica's board has made it plain to the bankers that all options are on the table.

The engagement of Navigant is a significant milestone for our company.

Few small Australian companies ever get a major New York Investment Bank to represent them in the sale or licencing of their products.

Investment Banks only get paid on a successful transaction.

Investment Banks never take you on unless they feel there is high likelihood of success.

I will now go on to summarize where we think we are with the product development and commercialisation of both the PeriCoach and the AutoStart Burette.

We have developed and got to the market the PeriCoach V3 which as I have previously stated is a digitalised pelvic floor physiotherapist.

Nobody else has done this.

We have strong clinical evidence and real-world data from the US and Australia supporting the clinical claims for the PeriCoach V2 and V3.

The pelvic floor market is a massive global market which is currently unmet.

There is currently no major multinational in this space.

We see the PeriCoach as the first line alternative to pelvic floor surgery and in the most severe cases as an adjunct to surgery.

Before I end this address, I would like to make mention and thank the Analytica staff who have worked so hard on the AutoStart Burette and the PeriCoach.

I personally am very proud of what our team have achieved.

I know the PeriCoach will in a very short time improve the lives of countless millions of women around the world.

I also would wish to take this opportunity to thank our shareholders who have supported us over the long



years of development.

The board and I are grateful for your support.

Before I finish I wish to thank two of our long serving directors Warren Brooks and Carl Stubbings who have worked so hard to help get Analytica to where it is today.

Both Warren and Carl's term finish today.

Warren has been with us for 6 years. Warren was invited onto the board as the board at that stage felt that we needed somebody with stock broking experience to help us with capital raisings, the success of such has been critical for the survival of Analytica.

Carl Stubbings has been working with us for 4 and a half years. Carl was invited onto the board to help us with marketing especially in the US.

I wish to thank both Warren and Carl for the support and help they have given me over their time on our board.

I wish to also thank my fellow board members who also have worked hard and have also supported our capital raising.

Ladies and Gentlemen, it goes without saying that your board too have invested heavily in our company.

Like you, we too have a lot of skin in the game.

We believe in the PeriCoach and the AutoStart Burette.

As I have been saying for years, Analytica is a research and development company that has doggedly pursued its purpose and has developed 2 global products that will improve people's lives.

However, this can only occur by partnering with a multinational to fully exploit the potential of our products.

I believe Analytica's management and its board have done everything in its power to position our 2 lead products to be Deal Ready.

Now it is up to the Banker.

Dr Michael Monsour, Analytica Chairman.

www.pericoach.com

www.analyticamedical.com



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



#### **About Analytica Limited**

Analytica's lead product is the PeriCoach<sup>®</sup> 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, and the USA.



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# Chairman's Address AGM 30 November 2017



### Forward-Looking Statements

This presentation contains forward-looking statements that involve risks and uncertainties.

Although we believe that the expectations reflected in the forward looking statements are reasonable at this time, Analytica can give no assurance that these expectations will prove to be correct.

Actual results could differ materially from those anticipated. Reasons may include risks associated with medical device product development and manufacture, risks inherent in the regulatory processes, delays in clinical trials, risks associated with patent protection, sales estimates, success of future activities, future capital needs or other general risks or factors.

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## Promises made at last AGM

- Develop and Market PeriCoach V3
- Collect evidence that the PeriCoach V3 works better than V2 and other devices on the market
- Shore up share registry to prevent a hostile takeover
- Fix up the balance sheet
- Restructure the board

ERICOACH

Compile resources to assist a commercialisation partner

ASX:ALT

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• Appoint an Investment Banker



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# **CEO** Presentation

# Analytica AGM 30 Nov 2017



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### Analytica's PeriCoach System

- PeriCoach includes a device, smartphone app and secure portal which allows patients and their clinicians to track and monitor progress.
- Addresses a significant unmet medical need with up to a billion women estimated to be affected by urinary incontinence worldwide.
- Designed in Brisbane, and Manufactured in Melbourne & Sydney, Australia.
- Already has all necessary regulatory clearances in US, Europe and Australia for urinary incontinence (UI) and improved sexual function.
- Patents pending or granted in major jurisdictions worldwide.





## The Value of PeriCoach

ERICOACH

- Massive, unmet market with a global clinical drive towards conservative treatments
- PeriCoach is a plug and play acquisition for a global licensee
- Already has required major regulatory clearances FDA, CE, TGA
- Immediately scalable manufacturing process using highest quality contract manufacturers
- Immediately scalable sales and logistics system
- Virtual Data Room ready and being continually updated
- Marketing playbook from in-market experience
- Roadmap of improvements planned with plans, specs, costings, and milestones – New hardware, New indications, New functionality, New markets, New evidence.
- Has a strong, demonstrated potential in additional markets.



### Overview of Last 12 Months

- V2 Clinical Trial concluded and results analysed
- 8-week challenge programme launched
- Version 3 brought to market gathering real-world data
- Updated App Styling, Bladder Diary, Surveys, Technique Feedback
- Data mining tools implemented
- Change in Pelvic Floor health landscape Mesh Implants, Class Actions, Vaginal Rejuvenation
- Data room established and process to secure licensing or acquisition partner underway





Randomised Controlled Clinical Trial was conducted (Australia, 2015/16)

Clinician Assisted Pelvic Floor Muscle Exercise (PFME)

VS

ERICOACH

Clinician Assisted PFME *plus* PeriCoach (Version 2) at home

• Quality of life measurements showed statistically significant superior results (p-value = 0.015) for the PeriCoach group over the control group.

BUT

- The level of clinical intervention in both groups far exceed that of a normal UI sufferer seeking treatment Not representative of the real market.
- Women required <u>8 visits to the clinician study site over 20 weeks.</u>
- These onerous requirements led to slow recruitment rates.
- We realised that we can get better data from real patients using V3.



### PeriCoach Version 3

#### Released May 2017

- Additional sensors measures movement in connection with the force sensors.
  - Algorithms tells a woman if she is exercising properly by examining her technique and scoring against our proprietary movement library.
  - Drives motivation, compliance, outcomes.
- Improved power management and better connectivity.
- Data systems development Data mining is providing powerful and previously inaccessible clinical, marketing and product development insights.





## 8 Week Challenge

#### Released May 2017

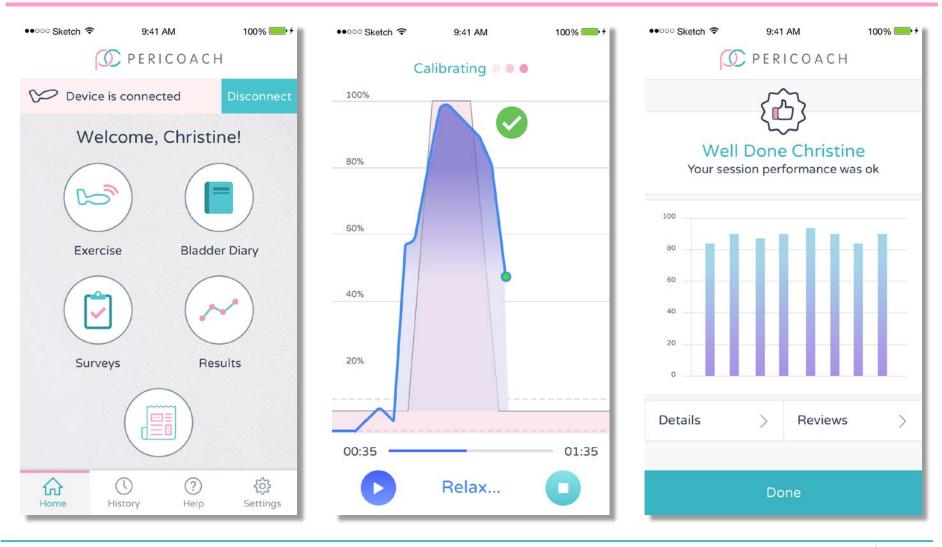
- Opt-out exercise programme for new patients.
- Provides structure and manages expectations.
- Combines exercises, strength testing, bladder diary entries, and quality-of-life surveys.
- Drives motivation, compliance, outcomes.
- Programme being adjusted to improve compliance based on evidence.





## Updated PeriCoach App - Usability

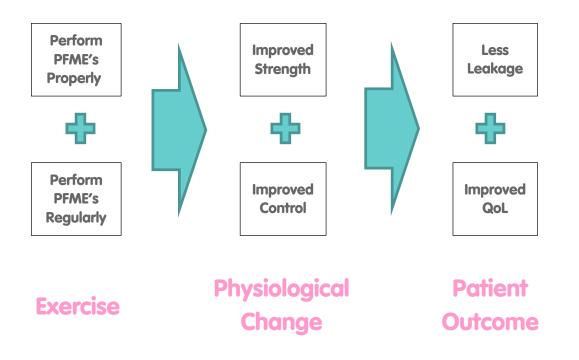
PERICOACH





### Why is Data So Important?

The Clinical foundation of PeriCoach is... If you perform your pelvic floor exercises properly and regularly, you will improve the strength and control of your pelvic floor, which will lead to less leakage and make you happier.

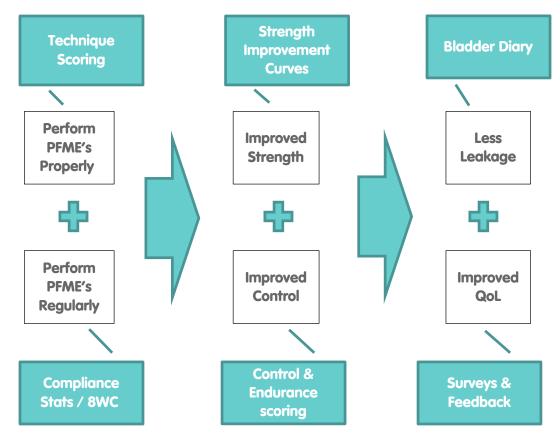






#### Measurement

You can't manage what you don't **measure** 

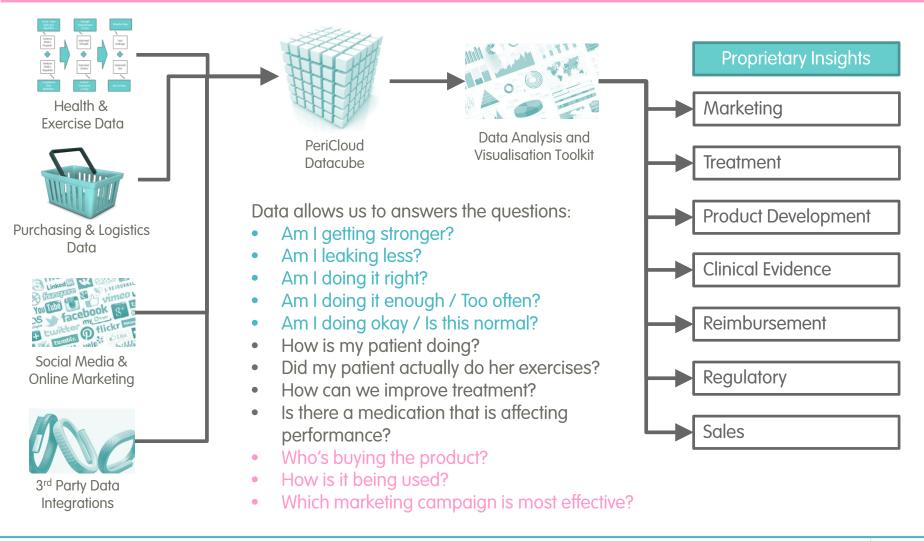






### The Power of Data

PERICOACH





## Technique Scoring

Each squeeze is scored for technique using a proprietary algorithm against a library of technique signatures developed with key pelvic floor experts.



## Technique Intervention

- Game-changing treatment innovation
- PFME is known to work *if* the woman does it correctly. When they don't, they give up.
- ~50% of women can't do their PF exercises correctly,
- $\sim 60\%$  of women don't want to talk to their clinician,
- ...and when they do, they are usually just dismissed with a pamphlet on PFME.
- Technique scoring has the ability to algorithmically identify patients with poor technique early in the treatment programme.
- Actively providing technique guidance is expected to result in a massive increase in effectiveness of PFME using PeriCoach over DIY or a competitor's product.





### Additional Market Opportunities

- Pelvic Organ Prolapse indication Pelvic Floor Muscle Exercise suggested for women with asymptomatic Stage 1, 2 or 3 prolapse. 45% of women over 40 affected.
  - Estimated average of 200,000+ surgical interventions annually in US
  - US Total POP Potential Market = 3.2% or 14 million women
  - Company is currently preparing documents to seek regulatory clearance for POP.
- Prophylactic Pre-Pregnancy and Post-Natal Markets PFME is already widely recommended during pregnancy and to post-partum women to reduce the risk of SUI.
- Female Sexual Dysfunction Indication a complex condition which may develop from number of contributing psychosocial and physical factors, including UI.





### Additional Market Opportunities

- Sexual Wellness Market PFME done properly has been shown to influence improvement in sexual function even in women who do not report any dysfunction. PeriCoach V2 Clinical Trial demonstrated that the PeriCoach group had statistically significant greater improvement in sexual function over those doing PFME alone.
- Fitness Market UI is known to be highly prevalent in sportswomen, even young, nulliparous women.
- As a complementary conservative adjunct to more expensive and risky interventions. PeriCoach data can provide evidence to a surgeon that a patient has performed her conservative treatment correctly and as prescribed, before discussing drugs or surgery.





## Value to a Sling/Mesh Implant Manufacturer

- Risk mitigation for existing suite of products investment and market protection
- PFME recommended by the American College of Physicians (ACP), the American Urological Association (AUA), and the Society of Urologic Nurses and Associates (SUNA) as first line conservative treatment prior to surgical intervention.
- PeriCoach provides independent documentary proof that patient has complied with conservative treatment
- Provides evidence point for legal risk mitigation for surgeon and implant manufacturer.
- A low cost 'insurance' compared with surgery costs.
- Expected better patient outcomes.
- Allows a sales team to provide full treatment spectrum offering.





#### Next 12 Months

#### **Evidence and Enhancements:**

- The Deal.
- POP Indication.
- Technique intervention capability.
- Real world analyses and research papers.
- Big data connections.
- COGS reductions and production streamlining for future owner.
- Database enhancements, increased analysis capability and reporting.





## Takeaways

- We're doing what we said we would:
  - 1. Build Best in Class
  - 2. Prove it Works
  - 3. Make the Deal ... *watch this space*
- We are doing things that nobody else can.
- With the right partner we have a unique opportunity to make a meaningful change in Women's health.





# **QUESTIONS FROM SHAREHOLDERS**



