

# ANALYTICA

## CEO Presentation to AGM

24 November 2015



# Forward-Looking Statements

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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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# The Benefits Of PeriCoach®

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## **Unique: measures the muscles that matter:**

- PeriCoach is the only treatment on the market that directly measures pelvic floor muscle strength – the ‘squeeze’ on the urethra
- Training these muscles is the first-line treatment for stress urinary incontinence

## **Provides real-time, previously unobtainable data:**

- Provides real-time feedback via a smartphone so patients can instantly view their progress
- Patients and clinicians can readily monitor strength improvement
- GPs and surgeons can guide rehabilitation and pre-habilitation
- Data collection and analysis is central to the PeriCoach strategy

## **Safety:**

- PeriCoach is registered as a medical device for SUI treatment, other indications to follow
- Regulatory clearance in Australia, Europe and the US

# Valuation

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- **Huge market opportunity:** stress urinary incontinence affects 1 in 3 women worldwide. SUI is just part of the picture.
- No dominant market competitors – **alternate therapies unattractive**
- PeriCoach is **a superior technology** - only medical device of its kind that measures the muscles that matter
- Field data, case studies and testimonials show **the product works**
- **We have achieved our key milestones:** Regulatory approval in US, Europe and Australia
- **Initial sales and marketing strategy** underway in Australia, the US, UK and Ireland:
  - Bottom-up: direct to consumer marketing campaign including social media
  - Top-down: practitioner awareness campaign
  - PR campaign
  - Services agreement with Salesforce4Hire to grow sales in the US

# Goal

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To enter into a partnership / licensing agreement with one or more major medical device sales organisations

- De-risk:
  - Regulatory Approvals – CE, TGA, USFDA
  - IP Protection – Patents pending, design registrations, trademarks, long lifespan
  - Manufacturing – Scalable, robust, economies of scale
  - Product pipeline – New features, new indications, new markets
  - Market acceptance – Sales, brand awareness, scalability
  - Evidence it works – Clinical trial, field data, publications, testimonials
  - Timelines – Deal-ready, can slot into a product portfolio immediately

# Clinical Trial

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- Recruitment proceeding.
- Post-clearance. Not required for any regulatory reasons
- Main outcomes:
  - Independent evidence. Ante for partnerships with many organisations.
  - Data → SUI Quality of life = function (pelvic floor strength)
  - Data → Using PeriCoach = Health Economics value \$\$\$
  - Data → Female sexual function = function (pelvic floor strength)
  - Additional research papers

NB: control group = highly artificial, best-case alternative treatment = Women trained to do PFME's, with clinician visits every 4 weeks.

In reality, women often do not know how to do their PFME's correctly, and would not do them without the clinician intervention. The prevalence of SUI is proof of this.

# Pipeline

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- New sensors being implemented into production now (patents pending)
- New indications from case studies and real patient successes using PeriCoach:
  - Pelvic organ prolapse
  - Lower back and supra-pubic pain
  - Faecal incontinence
  - Overactive bladder
  - Sexual function market – damage to PF means less sensation. PFME anecdotally known to help.
- Pregnancy – preventative use of device opens market to majority of women.
- Additional software features, including a teaching platform
- Additional data analysis capabilities

# Australia - Sales Launch

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- Version 2 product developed from Controlled Market Release feedback in 3Q 2014
- Sales launch in Australia in January 2015
- Direct to consumer marketing started after iOS clearance of v2 product
- Our goals:
  - To get early revenue
  - To gather more field efficacy evidence, user feedback, and product development ideas
  - To develop a marketing strategy and experience that would be valuable to a larger marketing and sales partner



# UK and Ireland – Sales Launch

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- CE clearance in Oct 2014
- Launch in June 2015
- UK sales launch: entry point into continental EU
- Our goals:
  - Build a presence and accumulate clinical evidence in home markets of major European medical device multinationals
  - Revenue

# US – Sales Launch

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- USFDA 510(k) clearance in March 2015 – 78 Days!
- Launch in June 2015
- US different as perineometers are Class II medical device and currently available by prescription only
- Our goals:
  - Achieve over-the-counter registration in the US, removing the need for prescription and opening the market up for a potential partner for direct-to-consumer sales
  - Build a presence and accumulate clinical evidence in home markets of major US medical device multinationals
  - Revenue

# Looking ahead – 2016

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- Over-the-counter submission to the USFDA
- Potentially new indications for use in ANZ, CE, and rest-of-world: Overactive bladder, Pelvic organ prolapse, lower back pain and supra-pubic pain, female sexual dysfunction, faecal incontinence
- Completion of randomised controlled clinical trial now underway in Australia
- Additional functionality and product iterations (device and software)
- Continued publication programme – case studies, posters, peer reviewed papers
- Partnerships with industry bodies, domestic in AU, EU, and US and globally
- New marketing campaigns
- Opportunistic expansion into new geographic markets
- Data mining and new therapeutic insights unique to the PeriCoach.
- Increasing sales

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Thank you for your continued support

