

Analytica Annual General Meeting Chairman's Address

24 November 2015 - Dr Michael Monsour

Good morning ladies and gentleman and welcome to Analytica's Annual General Meeting for 2015.

Today I wish to spend some time outlining our strategy to develop shareholder value.

Analytica is a medical device research and development, and commercialisation company. The way we will develop value for our shareholders is to work to our strengths.

Our objectives therefore are as follows:

1. to build the best-in-class product,
2. to comprehensively prove that the product works,
3. to raise market awareness and acceptance of the product; and
4. to look for partnership opportunities with multinational medical device companies with the scale to make this product a global success.

We have made real progress over the past few years towards achieving these aims. Our efforts in the research and development area gives us confidence that we have developed the best-in-class registered medical device which is years ahead of any competitor.

We have worked with world-class medical device manufacturers in Australia to produce the PeriCoach, secured patents over this intellectual property and developed a product with an interface that is intuitive and easy to use for both the patient and clinician.

We have also established a two-year pipeline of further enhancements to the PeriCoach with the aim that we keep ahead of any potential rivals in this field.

We have secured key regulatory clearances for PeriCoach as a medical device, providing the regulatory foundation to supply the product globally.

Following our sales launch of the product in Australia in January and the UK and US in June, initial sales are encouraging. These sales will help ensure clinicians become comfortable with advising their patients to purchase the PeriCoach.

We have developed a manufacturing capability for the PeriCoach which is high-quality, robust, scalable and owned by Analytica.

Our analysis of the data provided by existing PeriCoach users shows that the product does work to strengthen the pelvic floor muscles. This is further supported by the compelling evidence from clinician case studies, papers and



patient testimonials. The most gratifying point is that this data shows that PeriCoach is making a real difference to women's lives.

We are also conducting a post-approval clinical trial, the primary goal of which is to provide data for health economics studies of PeriCoach. This trial will give us independent evidence to give to the health departments and private health insurers around the world so that the use of the PeriCoach is funded by these agencies.

The trial will also examine the role of PeriCoach in relation to Female Sexual function – the first clinical trial of a medical device to treat the condition. We expect results of the clinical trial in 2016.

We think the PeriCoach is a great product, but product development doesn't stop when you release the first product for sale. Analytica's product development team has a two year pipeline of further enhancements to the PeriCoach to keep us ahead of any potential rivals in this field.

In terms of partnering with multinational medical device companies, I would like to explain the reasoning and strategy behind this in more detail.

There are only two ways we can realistically reach our goal of selling PeriCoach globally.

We could do this ourselves, but with a limited marketing budget this would take years and be a long hard slog.

In many ways, we are exactly the same as an Australian biotech company with a worldwide product.

Nobody expects an Australian biotech company to market their product worldwide. Australian biotech companies develop products and then license them to a multinational that already has established distribution channels in place.

We need to do likewise and that is our aim. Analytica aims to make PeriCoach so attractive that multinational medical device companies will want to partner with us.

However, the difference between the PeriCoach and a biotech company's product is that the PeriCoach is now ready for global sales whereas a biotech's pharmaceutical product usually takes years to get to the market and for royalties to roll in once a licence deal is signed.

In the case of the PeriCoach, royalties can occur immediately once we sign any potential licensing deal.

So what do major multinational medical device companies want?

1. They want a product that works that is ahead of everything else in the market place.
2. They want a currently unmet massive market.
3. They want strong IP.
4. They want worldwide registration.
5. They want clinician endorsements especially in the key markets of the US, UK and Europe. We tick this box.
6. They want a first quality manufacturing process that can quickly be scaled up.
7. They want a pipeline of product enhancements than will keep their product ahead of any competitors. ie. iPhone 1, 2, 3 etc

With the PeriCoach, Analytica can offer all seven points to a potential multinational partner - they want a product



that has been tested in the market place, that is ready to go and has been de-risked and we have done this.

Our strategy is to approach any potential partner once we have the results of the clinical trial. The independent data and the health economics outcomes are important, but the trial's secondary endpoint examining Female Sexual Dysfunction is equally exciting.

Let me spend some time explaining how important this indication is for us and what a positive result could mean to Analytica and any potential licence deal.

I believe that a positive Female Sexual Dysfunction result will be an inflection point for valuation of any license deal for the PeriCoach.

Currently the market for the PeriCoach is the 1 in 3 women who suffer from damaged pelvic floor muscles especially stress urinary incontinence. An extremely large market in anybody's language.

However, if the PeriCoach does improve Female Sexual Dysfunction then this Stress Urinary Incontinence market is dwarfed by the 60.5% of Australian women reporting at least one sexual problem within the preceding year.

So if we look upon the market as a funnel, the funnel is doubled if we add Female Sexual Dysfunction to the Stress Urinary Incontinence market.

Just one indication of the size of this market is the recently approved drug for Female Sexual Dysfunction, Flibanserin also called Pink Viagra. A day after getting FDA approval for it, Sprout sold it to Valeant Pharmaceuticals for US\$1 billion upfront plus milestone payments plus a royalty.

The drug works only in 10% of patients and causes hypotension and Central Nervous System Depression in women taking it. Women cannot drink any alcohol what so ever while taking the drug. It currently costs the patient US\$800 per month in the US.

As already stated, it is our strategy to approach major medical device multinationals with view to a potential licence deal once we have concluded the clinical trial for Female Sexual Dysfunction.

However, as of today, we are already speaking to six major multinational medical device companies who have directly approached us because they are interested in the PeriCoach. Discussions are in an early stage regarding potential cooperation and synergies and we have indicated that we are interested in doing a deal after we have the results of the clinical trial.

We are also looking at another potential indication for PeriCoach to treat pregnant women. We have been told by leading US based doctors that they want to use the PeriCoach in pregnant women as they believe using the PeriCoach during pregnancy will reduce the incidence of stress urinary incontinence and other pelvic floor disorders post-partum.

If this is so, then the market is further enlarged to include all women who get pregnant.

The funnel that went from 30% for Stress Urinary Incontinence to 60% of women for Female Sexual Dysfunction will now go to nearly 100 % of women if we can prove that the use of the PeriCoach while pregnant reduces damage to the pelvic floor.

By pursuing these additional indications for PeriCoach means we potentially have multiple revenue streams for the product and further de-risk our business model.



Our appointment of Dr Thomas Lönngren to the Board will enhance our sales and marketing and partnering efforts. Thomas has a distinguished career serving as a top international regulator for over 25 years having been head of the European Medicines Authority – the regulatory authority for the EU for 10 years. Thomas now works as a strategic advisor to major multinational pharmaceutical and medical device companies both in Europe and the US. We are extremely privileged to have such a high-profile international director on our board who has extensive networks with the decision makers in these companies.

Fuelling our extensive development and marketing program has been the successful capital raising in August which raised a total of \$2.9 million.

We also expect in the coming weeks to receive a research and development tax incentive worth nearly \$2 million. R&D research grants such as this have enabled your company to invest in critical research to develop our world class product, the PeriCoach and we acknowledge and appreciate that support from the Australian Government.

I would like to thank my fellow board members, the CEO Geoff Daly, the engineering team and the marketing team for their efforts of the previous twelve months to ensure that the company continues to improve into the future.

I would also like to thank you, our shareholders for your continued support during the past year and we look forward to an exciting year ahead as we make further progress with our commercialisation of the PeriCoach.

For more information about the PeriCoach System, visit: www.PeriCoach.com

For more information about Analytica, visit www.AnalyticaMedical.com

Follow us on:



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. The product has USFDA 510(k) clearance. The product has been on sale in Australia and New Zealand since January, and recently launched in the UK and Ireland, and in the USA. 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.



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Annual General Meeting 2015

Chairman's Presentation



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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Strategy to develop shareholder value

- Develop best in class registered medical device
- Develop a user interface for both patient and clinician
- Secure strong IP to protect our property
- Secure worldwide registration as a medical device
- Work with world class medical device manufacturers
- Develop manufacturing capacity can is easily scaled up
- Secure initial sales in US, EU/UK, Aus/NZ
- Have a two year pipeline of enhancements
- Conduct a multi-centre trial on health economics and Female Sexual Dysfunction



Strategy to market PeriCoach®

- Small company with limited resources
- Global product, second to none
- Two ways to reach our goal
 - Market ourselves – will take a number of years due to a small marketing budget
 - Make ourselves attractive to a multinational medical device company
- We aim to do a license deal with a multinational



What do multinational device companies want?

- ✓ A product that works and is ahead of everything else in the market
- ✓ A currently unmet massive market
- ✓ Strong IP
- ✓ Worldwide foundation for regulatory clearances
- ✓ Clinician endorsements in the key markets of US, UK/EU, Aus/NZ
- ✓ Quality manufacturing process that is easy to scale up
- ✓ A pipeline of product enhancements to keep the product ahead of the competitors

When do we approach a multinational?

- The best time is once the results of the clinical trial are available.
- The trial encompasses Female Sexual Dysfunction (FSD) and this is a market of approximately 60.5% of women.
- A multinational will only pay for indications that we have evidence for, this is why the completion of the trial prior to approaching a multinational is important
- **Indication of market size:** Flibanserin (pink Viagra) only works in 10% of patients, has a number of adverse side effects, but was part of a deal for US\$1 billion upfront plus milestone payments and royalties.

What does a typical license deal look like?

- Upfront payment
- Milestone payments
- Royalty payments of between 5-15%
- Valuations will depend on commercial tension between competing bidders

