



ANALYTICA LTD - ABN 12 006 464 866

ASX ANNOUNCEMENT

Analytica Annual General Meeting – Chairman's Address

22 November 2018.

Good morning Ladies and Gentlemen and welcome to the 2018 AGM of your company, Analytica.

My emphasis today is to inform our shareholders where we are with this commercialisation process for both the PeriCoach and the AutoStart Burette. I will also outline our next steps to achieve the right deal for Analytica.

Before I talk about this, I will first discuss what we have achieved in the 12 months since our last AGM.

2018 Achievements

On the 2 May this year Analytica announced to the market that it had received Australian Therapeutic Goods Administration clearance for the expanded clinical indication for the PeriCoach System to assist in the conservative treatment of Pelvic Organ Prolapse.

To the best of our knowledge the PeriCoach is now the only pelvic floor muscle rehabilitation system indicated for Australian women to target resolution of symptoms for mild to moderate pelvic organ prolapse. This adds to our indications for urinary incontinence and sexual wellness.

Pelvic organ prolapse is a very common and serious condition. Data suggests that 50% of women that have given birth have some degree of Pelvic Organ Prolapse and half of women over 50 complain of prolapse symptoms.

Estimates state women have a lifetime risk of up to 12% of undergoing a surgical intervention, with a reoperation rate of nearly 20%. Each surgical intervention in the US is estimated to cost between US \$10,000 to US\$20,000.

As the population continues to age and awareness of the condition grows, it is projected that the number of women with symptomatic Pelvic Organ Prolapse will increase up to 46%. Pelvic floor muscle exercises have been demonstrated to be an effective tool in treating women with mild to moderate POP symptoms.

This clearance from the TGA is significant in that the PeriCoach system is now indicated in Australia for the most common conditions stemming from a weak pelvic floor: urinary incontinence, sexual wellness, and pelvic organ prolapse. No other system on the market has this capability or registration.

We are now in the process of working on expanding our CE mark and compiling evidence for a new US clearance to include prolapse. This additional capability adds substantial value and progresses the sale or license of the company and PeriCoach system to a multinational".

On the 21st August this year Analytica announced to the market, the medical world and to the medical device multinationals the results of the Real-World study of the PeriCoach V3 using our 8 week challenge for stress urinary incontinence. This post-approval, all-comers observational study, reviewed women using the PeriCoach V3 system. The study was conducted in Australia, the UK and the USA.



The PeriCoach 8 Week Challenge provides users with reminders to exercise a minimum of five sessions a week, enter information into the bladder diary three days a week, and respond to a quality of life survey at onset, at four weeks and at eight weeks.

User-reported bladder diary entries were used to analyse leakage episodes and volume. Leakage episodes were measured by the number of events reported per week. Leakage volume was recorded by patients. The analysis of the PeriCoach real-world data was conducted by independent biostatisticians in the US.

This data revealed a dramatic reduction in both leakage events and urine volume within the first 3 weeks of use and a significant improvement in pelvic floor strength within just five weeks.

More than 60% of V3 users, using the device reported a highly significant reduction in both urine leakage episodes and urine leakage volume by week 3. By week eight, more than 75% of users have at least 80% improvement in both leakage episodes and leakage volume.

We now have irrefutable evidence that an improvement in pelvic floor muscle strength directly correlates with a reduction in both urine leakage events and urine leakage volume.

This is important as we now have strong clinical evidence which proves that the PeriCoach V3 not only works but we believe it is far superior to anything else on the market.

In October 2017 Analytica did a 1 for 8 entitlement offer which had 2 attached options for February 2018 and June 2018. This offer and the attached options were extremely well supported by our shareholders. One million and thirty-nine thousand came in in February this year followed by one million five hundred and thirty-two thousand dollars in June. Of course, in the coming months we are due to receive from the Australian Government our R & D credits.

This entitlement offer with the attaching options was to give us the flexibility so that Analytica would not be under any financial pressure to do the first deal that came along.

PeriCoach

Now I will address commercialisation of our products, which I am sure is the reason why you are here. However, I will first talk about the PeriCoach.

The last 12 months have taught us there are 2 broad groups of potential acquirers: Medical device companies and IT companies. However, the risk profiles of the 2 groups are different.

The medical device company's business model is to target doctors and physiotherapists in order to build the market for their products. They demand strong clinical data. These companies are not big into direct to consumer sales, especially sales via the internet, but prefer to sell their products via recommendation from clinicians.

The IT companies have a business model that targets women directly and not necessarily the medical profession. They are direct to consumer and hence clinical data and evidence is less important to these companies. Both these models suit the PeriCoach and our regulatory approvals from the FDA.

In the US we have FDA approval both for the sale of the PeriCoach via the prescription model as favoured by the medical device companies and over the counter FDA approval for direct sale to consumer as favoured by the IT companies.



The medical device companies require the following to reduce their risk: regulatory clearances, strong IP, strong clinical evidence and existing commercial marketing success.

When we look at what Analytica brings to the table with the PeriCoach we have: regulatory clearances, strong IP and irrefutable strong clinical evidence from our real-world study on the V3. What we lack is proof of commercial marketing success. This is understandable as Analytica is an R & D company. We are not a marketing company.

Both medical device companies and IT companies are all about risk mitigation. This risk mitigation is especially so for medical device companies, in the pelvic floor space after the sling and mesh disasters and the resulting litigation occurring worldwide.

There are usually two ways a medical device company takes on a new product.

They either purchase a new medical device very early on in their development before there has not been time to build value in the device. In other words, they purchase the IP early on before there is proven clinical data or marketing success. As a result, they purchase these products at a very low price. A low cost/low risk strategy.

The other way they do it is later in the product development cycle, once the companies have had time to add value. The product is mature with proven clinical capability and commercial success and is income positive from day one for the medical device company. This of course costs the medical device company very much more. A high cost/low risk strategy.

This is where the medical device companies require regulatory clearance, solid IP, strong clinical data and commercial marketing success.

The IT companies require regulatory clearance, strong IP, less clinical evidence and not necessarily marketing success, but a significant appeal.

So in order for Analytica to get full value for the PeriCoach and our AutoStart technology we need to structure the deal to mitigate the risk for the medical device companies of limited commercial marketing success.

With our bankers we have now developed a strategy that addresses this commercialisation issue and meets the demands of the medical device companies to lessen their risk and at the same time delivers Analytica shareholders full value for our IP.

AutoStart Burette

In 2010 Analytica signed an agreement with Medical Australia Ltd, to market and distribute the AutoStart and AutoFlush burette.

Prior to that agreement Analytica had a sales team in the field. Having our own sales team and managing distribution was unsustainable for us.

Regrettably in the following years Medical Australia Ltd went away from their core business into the veterinary business. Our product was neglected. With fresh management, Medical Australia divested the veterinary product line and went back to their core business of IV infusion sets.



In November 2017, Medical Australia was taken over by ICU Medical, a global US based medical device company. ICU Medical distribute and market infusion products and had recently acquired the large Hospira infusion division.

Medical Australia had achieved registration of the AutoStart burette with Queensland Health. As a result of representations, the minister for health and the director of Queensland Health supported a trial in Gladstone of our AutoStart Burette. This trial was extremely successful.

Analytica and ICU Medical are now collaborating to engage other hospitals in Queensland to trial and deploy the AutoStart Burette. With this reinvigorated relationship, and continued penetration of the Queensland hospital system, Analytica is building a strong commercial case with compelling risk minimisation, reduction of nursing time and a significant cost advantage for hospitals.

It is estimated that in Australia there are over 20 million infusion events a year, a very substantial market.

Conclusion

Ladies and Gentlemen before I finish let me summarise the key points:

- 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.
- We now feel we can offer the medical device companies a strategy that reduces their risks and at the same time enables Analytica to get full value for our technology.
- Likewise, the burette market is also massive. We believe that the traction we are now getting in Queensland hospitals will prove to the medical device companies that commercial success is possible with our burette technology.

Before I end this address, I would like to make mention and thank the Analytica staff, especially Geoff, Chelsea and Megan who have worked so hard on the PeriCoach and the AutoStart Burette. I personally am very proud of what our team have achieved. I feel that 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. I, and I know, the rest of your board are grateful for your support.

I wish to also thank my fellow board members Ross, Thomas and Peter, who also have worked hard to position our company to where it is today. We all believe in the PeriCoach and the AutoStart Burette.

However, we know that our products will only be successful if we can partner with multinationals.

I will finish by saying that I believe we will be successful.







For more information, please contact: investor relations@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.

