ANALYTICA

CEO Presentation to Analytica Annual General Meeting

28 November 2019

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.

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Strategy

Plan A – Global licensing / sale

- Multinational takes care of Marketing, Manufacturing, etc
- Analytica concentrates on product development – remains small.
- Significant interest but industry issues have so far prevented completion.

Plan B – DIY with regional distribution

- Each Country or Region adds overhead – Regulatory, logistics, IT and manufacturing.
- Manufacturing and post-market needs to be more closely controlled – ALT needs to take on more responsibility in-house.
- Can no longer remain a small company.

Regional Distributors

We are targeting existing, proven regional distributors in the personal medical device and/or urogynaecological space.

The distributors will provide/assist with:

- Local regulatory clearances – generally 6 months (China longer)
- Translations of websites, software, documentation content
- Logistics and customs clearance.
- Adapting / creating marketing materiel and techniques suited to local market, healthcare systems and customs.

Local trademarks are required

- Focus on per language rather than per country

Manufacturing

- COGS reduction project underway
- Primarily through redesign of electronics
  - Components going out-of-life
  - Cheaper and more powerful components now available
  - Clean up and simplify design
- Streamline supply chain.
- Absorb more manufacturing responsibility in-house.
- Aim for high-volume low-COGS manufacturing mid-2020.
  - Needed for distributor model
  - Opens possibility to sell via pharmacy chains

Manufacturing In-house

- Needed to ensure reliable supply and quality control.
- Staged in-sourcing with volume.
- Stage 1 – Take over final manufacturing responsibility
  - Requires ISO 13485, GMP certification
  - Assembly remains at contract manufacturer (CM)
  - Final testing and packing done by ALT
- Stage 2 – Redesign plastics for simplified manufacture
  - Assembly and test done by ALT
  - Parts moulding done by CM
- Stage 3 – Moulding in-house
- Stage 4 – Electronics manufacturing in-house

In-house IT and Call-Centres

- Architecture of Data requires specialist skills
  - Privacy
  - Data sovereignty
  - Volume and complexity of data
  - Data analysis
  - Multi-lingual Apps, websites, and helpdesk.
- Call-centre – we need to closely control:
  - Post-market regulatory escalation
  - Consistent messaging and training
  - Follow-up calls – pelvic floor exercise as a service

Regulatory

- CE-Mark for Pelvic Organ Prolapse in 2019
- USFDA clearance for POP is on hold
  - Difficulty finding a predicate
  - De Novo application required
  - Significant clinical evidence hurdle
- Regional clearances in partnership with distributors
- US QSR-compliant quality system operational in 2019.
- Also ISO 13485, but has not yet been certified - Planned.
- European MDR coming into force in May 2020.
- PeriCoach *may* be Class IIa in EU under the new software rules.
  - Clarification and guidance required from EU.
  - PeriCoach designed to be IIa anyway as it is Class II in USA

Clinical

- We know it works.
- Several presentations on RWD delivered to international audiences.
- Work on publishable papers on v2 RCT and RWD
- Small-scale independent trials underway (one in a US university)
- Significant interest for larger scale trials, especially for POP and prevention with assistance of governments.
- Continued gathering of RWD and analysis.