

# Minimally invasive treatment of PolyCystic Ovary Syndrome (PCOS) related infertility

## THE PROBLEM - POLYCYSTIC OVARY SYNDROME (PCOS) INFERTILITY

PCOS is a leading cause of female-factor infertility: >10% of women have PCOS, and half of them will seek fertility treatment. Many therapeutic strategies exist to restore ovulation in infertile PCOS women:

- 1st line drug-based treatment is effective but raises risk for multiples and has common side effects and resistance (at least 40%)
- 2nd line gonadotropin injections are complex, costly, raise risk for multiples and ovarian hyperstimulation (life-threatening)
- 3rd line IVF is costly and highly "medicalized"

## UNDERUTILIZED SURGICAL PREDICATE

Ovarian drilling is a laparoscopic surgery that corrects hormonal imbalances by destroying ovarian tissue, and often results in spontaneous ovulations (80% within 3 months) and pregnancy (60% within 6 months).

Despite numerous positive outcome studies on the safety, short and long term (>10 years) efficacy of the approach and favorable guidelines and reimbursement, adoption has been limited due to the following:

- Surgical nature of technique and need for general anaesthesia
- Procedure incompatible with skills and practice of fertility physicians
- Lack of facilitating technology

## THE ABLACARE SOLUTION - OVARIAN REBALANCING

AblaCare transforms the surgical approach into an office-based, ultrasound-guided treatment. AblaCare's technique, ovarian rebalancing, can be performed in the fertility clinic setting using the same minimally invasive access commonly used by fertility physicians for IVF egg retrieval. AblaCare's value proposition is the following:

- for patients: a more "natural" less "medicalized" treatment
- for payers: less costly, less invasive, less labour-intensive option
- for clinicians: less invasive procedure not requiring a referral, compatible with fertility physician setting and skillset.

## ACHIEVEMENTS TO DATE AND NEXT STEPS

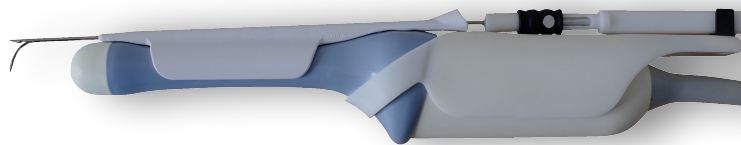
Since creating the company in September 2017, we have: completed our prototype development and pre-clinical validation, extended our IP portfolio, and de-risked our regulatory pathway by completing a pre-submission with FDA and EU notified body. We are currently preparing for our first clinical trial (planned to begin in early 2019), and are raising a \$10M A round to achieve CE mark and US pivotal study enrolment.

## WHO WE ARE

AblaCare is the sixth company created, funded and incubated by MD Start, and is based upon an invention from US industry experts in the field of ablation. The company is managed by a team of serial medtech entrepreneurs experienced in product development, validation and launch.

## HIGHLIGHTS

- 1-time, office-based, ultrasound-guided, transvaginal treatment to provide women with a more natural and less medicalized pregnancy experience
- Less costly, less invasive, less risky than currently solutions
- \$3B+ global addressable infertility market
- U.S. & EU Class II device
- Broad IP
- Currently raising \$10M A round



## WHAT WE DO

AblaCare is developing a device for the treatment of PCOS related infertility, based on an effective and demonstrated surgical predicate and an access and delivery path routinely used by fertility physicians. The device aims to replace the safe and effective, yet today rarely performed, ovarian drilling approach (performed laparoscopically) with a minimally-invasive approach.