

## **Investors Update**

## Investment

The second round of the Together equity crowdfunding has ended successfully, the company raised ~\$600K from the angels' club and another~\$500K through the equity crowd funding. The funds will allow Ark to continue moving forward towards FDA submission of LapBox V2 and initiate soft launch.

## Manufacturing

The company has finalized the design and testing of the LapBox V2 (seen in the pictured below). this is an advanced system with a bigger chamber, delivered through a smaller diameter delivery system.

The system is designed to be more cost effective to allow mass production thanks to changes of materials and design.

The company has signed a manufacturing agreement with a large Israeli medical device manufacturer, Mogo Afek (<a href="https://www.megoafek.com/">https://www.megoafek.com/</a>). Mego has extensive experience and expertise in mass production, RF welding and of construction made from polyurethane films.



### First In Human Clinical Trial:

The FIH trial has restarted in Carmel Hospital with Dr. Yuval Kaufman and Dr. Moran Paz. The first case was performed successfully on March 2<sup>nd</sup> for a removal of a 500-gram uterus using power morcellation.

#### FDA:

The company has successfully negotiated with the FDA and was able to reduce the number of physicians that will take part in the usability trial (part of the FDA marketing approval plan). The



reduction was approved due to Covid-19 restrictions on physicians, and it expect to expedite the physician recruitment.

### Team:

According to the growth plan Ark has hired 3 employees to expedite product development, manufacturing, regulatory approvals, and product launch:

- Ms. Wishahi Rina, (BSc mechanical engineering, MSc biomedical engineering) -project manager
- Mr. Yassin Orwa (BSc medical engineering) Quality Assurance
- Ms. Noga Rosen (BDES industrial design) Lab manager

## Intellectual Property:

The #4 patent has been submitted and is in provisional stage.

previous patents are being reviewed and the company's patent attorneys are negotiating their claims to achieve maximal protection over the companies IP.

# <u>Distribution Agreement</u>:

Ark has signed a distribution agreement with a leading medical device company for the distribution of LapBox for procedures involving power morcellation.

The distributor is a global company specializing in medical devices for the GYN laparoscopic field and has 100 sales reps in the US. The collaboration will assist in the LapBox market penetration in the soft launch and expose it to US physicians.

#### Future:

- Ark is moving ahead with the manufacturing and testing of the LapBox V2 and expects to start the FDA V&V testing in the coming months.
- Due to production delays and due to a request from the distributor for a prolonged shelf life, the tests will take longer than planed and the FDA submission is expected to take place in Q3 2021 instead of Q2.
- Ark is working on a low-cost version of LapBox that will include the chamber without the delivery device, this version will be offered in lower transfer price to assist in low budget markets.



- The company is working on adding US based KOL`s and is working with US hospitals to plan the product launch.
- Ark is continuing in communication with strategic partners and is conducting meetings with tier1 and 2 medical device companies.