

## **Ark Surgical Business Model Overview**

The following is an overview of Ark Surgical's (the "Company") commercialization plan and use of investment proceeds for the coming two-year period.

### **Key Goals and Activities – 2020: Infrastructure Setup**

The Company is currently running its First in Human study on 10 patients at Assuta Tel Aviv and Assuta Haifa.

During Q1 2021 the Company will submit its 510K to FDA and expects to receive market clearance by Q3 2021. It should be noted that the FIH study is not required for the FDA submission and is being conducted in order to support market acceptance during 2021, increase awareness for the device and exposure for the Company.

During Q3 2020 –Q1 2021 the Company will manufacture and test the units required for its FDA submission. The expected cost of goods for this initial limited run of commercial units is expected to be approximately \$250/unit. As part of this initial commercial production run the Company will also focus on streamlining its production process in order to reduce costs and to make it as scalable as possible in order to support larger quantities in the future. The likely scenario is transfer of production to one contract manufacturer which will source the various components and provide the Company with a finished product.

In parallel with the manufacturing and validation of the current device for FDA submission, the Company will continue to develop its Gen 2 device which will include several improvements and features that will be beneficial for eventual product launch such as upgrading the delivery handle to a plastic version (the FIH version is made of metal) which will also be cheaper to manufacture in commercial quantities.

During Q2 2021 the Company will also begin preparing for its pilot launch of the device which will begin by Q4-2021. This pilot will be geared to gaining initial market feedback, validating the market acceptance and business model and for increasing the Company's exposure and value which is expected to facilitate securing a strategic marketing partner for market expansion.

During 2021, the Company will also submit for CE Mark which it expects to receive during 2022 and which will allow for marketing and sale in the EU market and beyond. Although the Company will be focused on penetrating the US market, securing the CE Mark is expected to add significant value for the Company and will add to its attractiveness to potential marketing partners.

During this period the Company will use outsourced R&D services from companies with experience in design, development and also in conducting validations and verifications. As well, the Company will hire one R&D engineer and a part-time quality assurance professional in order to ensure that the Company's internal and external processes and procedures meet the required standards.

### **Key Goals and Activities – 2021: Pilot Product Launch**

During the second half of 2021 the Company will focus on selling its device in a focused geographic region of the US. In this region the Company will target approximately 3-5 hospitals and will work closely with surgeons who will use the device and will be willing to serve as champions for the device in the GYN field. The Company has already met with over 20 surgeons in the US and has identified potential sites for its pilot launch.

Since there are various surgical techniques for performing hysterectomy (manual morcellation, power morcellation, vaginal access, and open surgery) which are used by different surgeons, the Company will focus its pilot marketing on demonstrating LapBox value to surgeons using all these various

techniques. This will allow the Company to showcase the device’s versatility to the medical community as well as potential marketing partners.

The following potential sites have been identified based on initial discussions held during 2019:

Hospital	Demonstrate LapBox Value for Following Clinical Technique:
University of Chicago	Improved performance of lap hysterectomy with power morcellation
St. Mary’s (Waterbury, CT)	Enabling conversion of open surgery to lap surgery with power/manual morcellation
University of Miami	Improved performance of manual morcellation
Yale University	Enabling supracervical hysterectomies

Another key consideration in choosing surgeons for the pilot market release will be the surgeon’s connections with potential partner companies and their level of influence in the GYN surgical community.

As part of the initial pilot the Company will seek to generate clinical data that will be presented in journals, conferences, etc. and will implement a targeted media campaign to increase awareness for the device in among medical societies, women’s health support and advocacy groups and industry.

It is expected that during the soft launch the Company will succeed in selling 100 units and will sell at a market price of \$350-\$500/unit. This quantity, together with enthusiastic feedback of surgeons and the high level of market awareness for a user friendly solution, is expected to result in the Company securing a marketing partnership with a manufacturer with established channels in US and OUS hospitals which will take on the sales and marketing and expand the market penetration of the device. Distribution agreement(s) agreement is expected to be entered during 2022.

During Q4 2021 the Company will hire a marketing and sales manager who will have experience selling laparoscopic surgical instruments directly to US surgeons and hospitals. The manager will have experience developing value models which will be required in order to facilitate adoption of the device by hospital value analysis committees. The manager will work with healthcare economic consultants in order to develop the required models. The manager will also work with experts to develop suitable training procedures and processes for training users on the device.

Together with the recruitment of the marketing manager, the Company will open a US office in order to fully support its US activities and to meet market and regulatory requirements.

Towards the end of 2021 the Company will also hire an operations manager who will manage all areas of the Company’s operations (supply chain, logistics, shipping, inventory, suppliers, subcontractors, etc.).

**2022 and Beyond (profit expected on 2023):**

Due to the period of integration of the Company’s device into the product line and sales process of the marketing partner, modest sales of the device are expected during 2022 with significant sales beginning in 2023.

The assumed scenario for selling via a marketing partner will be that the Company will continue to manufacture and sell its device to the marketing partner (the arrangement between Advanced

Surgical Concepts and Olympus). The Company will sell the device to its partner at an estimated transfer price of \$250 and the production cost is expected to drop to \$80 and then \$50 due to cost reduction, streamlining and increased volumes.

In the event that a marketing partnership is not secured by early 2022, the Company will consider alternative options for expanding its sales of the device during 2020 onwards such as using independent reps. Using independent reps is considered to be the most streamlined and focused method of selling to US hospitals and also provides maximum flexibility for the Company should it eventually secure a partnership.

The end user price is expected to decline slightly from 2022 due to potential competitors and other factors. The cost of goods as well is expected to decline with increasing quantities and additional cost reduction changes.

The Company has assumed that its marketing partner will not take on the manufacturing of the product which can be expected to reduce the cost per good but would change the revenue scenario to a royalty-based projection. It is expected that should the partner wish to manufacture the device as well it is likely that the partner will prefer to acquire the asset or the Company.

#### Headcount

The following is the expected personnel requirements to support the above-described business plan:

	<b>2020</b>	<b>2021</b>	<b>2022</b>
CEO	1	1	1
R&D	1 (part time)	1	1
QA Manager	1 (part time)	1 (part time)	Expand to full time
Operations Manager	--	1 (part time)	1
Marketing Manager	--	1 (full time)	1
Business development	1 (part time)	1 (part time)	1 (part time)
Medical director	1 (part time)	1 (part time)	1 (part time)