

# The Next Revolution in Endoscopic Ultrasound Guided Biopsy Products




Assaf Klein, CEO  
Carl Rickenbaugh, Chairman  
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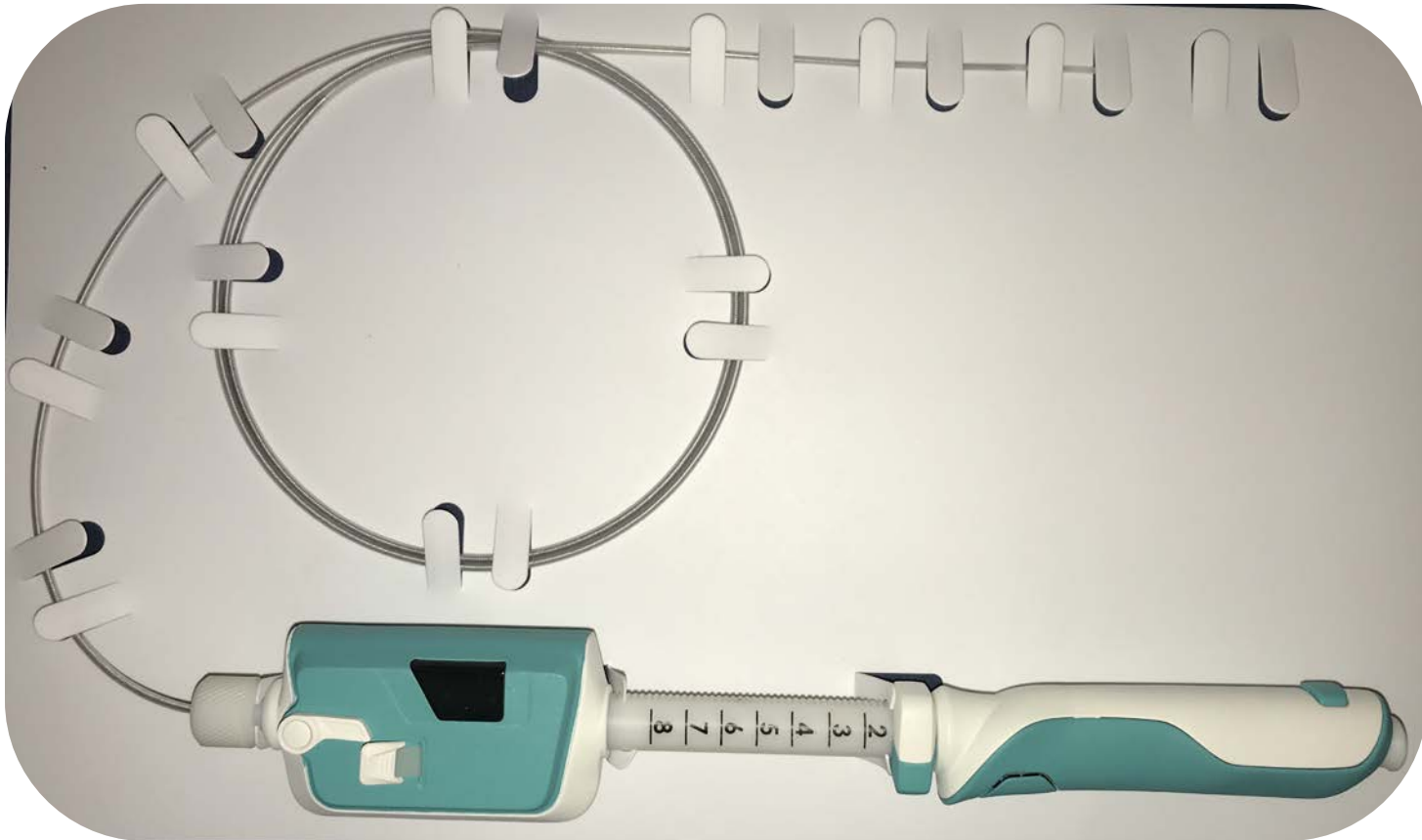
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# Limaca, Brief Overview

- **Product:** KORA, an electro-mechanically driven Endoscopic Ultrasound (EUS) Guided Biopsy Product for improved tumor diagnosis of GI system tumors
- **Clinical study:** Q1 2019, acute study, 1 week follow up
- **Strong team:** Led by three highly accomplished executives with medical endoscopic, medical device engineering, and biopsy medtech expertise
- **Investors:**  trendlines  
medical • agtech • labs

Limaca's groundbreaking biopsy product will advance precision medicine and enable improved diagnosis and prognosis.

# KORA, Revolutionizing US Guided Endoscopic Biopsy Products



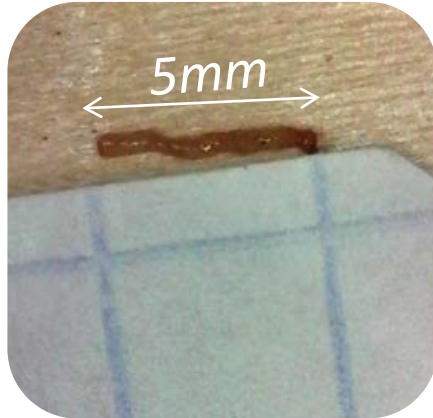
- KORA obtains **higher quality core tissue** for
- superior histopathologic analysis
  - improved diagnostic accuracy
  - better clinical outcomes

# Electromechanical Core Tissue Cutter

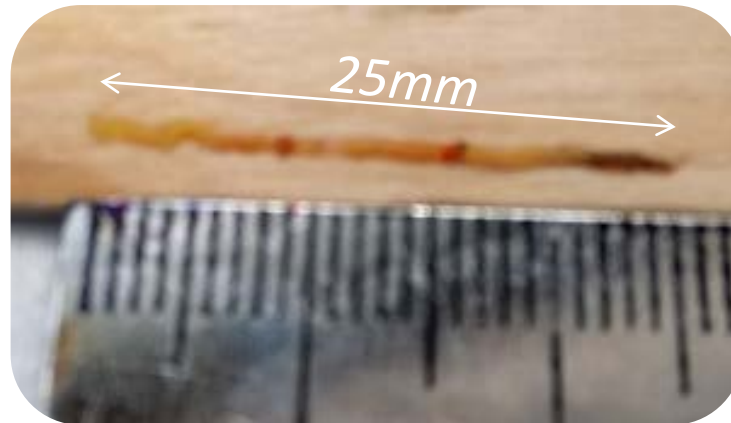
Proven superior sampling  
v. today's best performing manual product

**KORA GI 22G**

Obtained better core samples

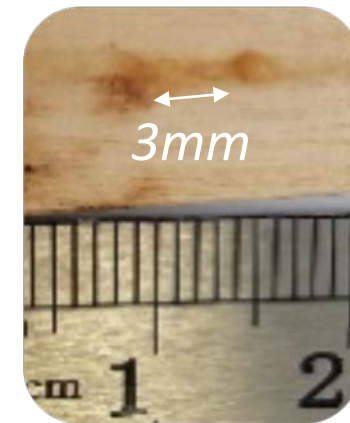


Single sample



Multi sample  
3 stabs

**SharkCore 22G (Medtronic)**  
Control



Multi sample  
2 passes X 10 stabs

# Limaca's Initial Focus: Pancreatic Tumors

- **55,000 Americans** will be diagnosed with pancreatic cancer this year<sup>1</sup>
- **44,000 Americans** will die of pancreatic cancer<sup>2</sup>
- **9%** survival rate
- Every pancreatic tumor is different, requiring specific diagnosis<sup>3</sup>



**Future product includes endobronchial ultrasound guided transbronchial needle biopsy for lungs**

Sources:

1 and 3: Pancreatic Cancer Network

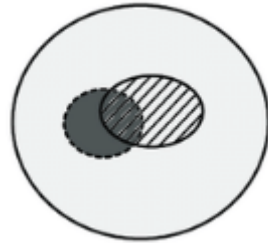
2: American Cancer Society

# Current Biopsy Products are Inadequate...

Limitations of **manually operated** Endoscopic Ultrasound (**EUS**) Fine Needle Aspiration (**FNA**) and Fine Needle Biopsy (**FNB**) products



Multiple stabbing of lesion (often 20-70x)



Imprecise stabbing



70-80% tissue acquisition rate



Small sample suitable for cytological (cell) analysis only

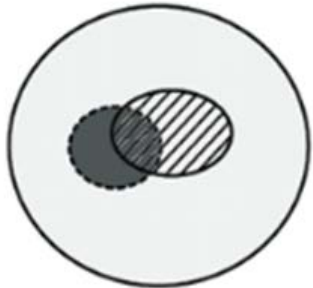
# ...The Result



- Injury to organ tissue
- Significantly longer procedure



- Of 10 biopsies, 2 to 3 will fail
- Patients need to come back for repeat procedures



- Additional stabs and time to reach the target tissue
- Frustrated gastroenterologist



- Unable to perform advanced analysis \*
- Inability to provide personalized medicine \*

\* **The limitation to obtain only a small sample** suitable for cytological (cell) analysis only, means that advanced analysis of tumor type cannot be performed, so therapy cannot be tailored to the exact tumor type, potentially resulting in suboptimal therapy. Advanced analysis involves molecular profiling: analyzing patient's DNA, RNA, and protein in cancer cells



# KORA GI: Win-Win for All

*"We must have needles that provide a higher tissue yield with fewer passes, to improve diagnosis and drive patient specific therapy to achieves better outcomes"*

Robert Hawes, MD

Medical Director, Florida Hospital Center for Minimally Invasive Therapy



## Physician

- Better quality sample
- Larger tissue sample
- One needle pass and fewer stabs (lesions)
- Improved acquisition rate



## Patient

- Improved diagnosis
- Better prognosis
- Reduced risk of infection and hospitalization
- Enables personalized medicine



## Healthcare facility

- Quicker procedure (estimated savings ~10-15 minutes)
- Reduced need for repeat biopsy procedures
- Reduced risk of potential complications

# IP, Regulatory and Reimbursement

- Robust patent protection
- CE and FDA submission will follow clinical study
  - CE Class IIa
  - FDA Class II, 510(k) pathway
- Reimbursement codes in place

# Global Endoscopic Ultrasound Biopsy Product Market

*attractive market, responsive to better technology*

1.1 million procedures • \$300 million market

## Major market players today

*None have electromechanical products, all are manual*



**Medtronic**

Boston  
Scientific

COOK  
MEDICAL

**OLYMPUS**



## Potential for New Entrants via Acquisition:

Many Additional Large Global Medical Device and Diagnostic Companies are looking to expand their oncology and surgical product portfolios. So, there is high potential for Limaca to attract additional potential acquirers **seeking to enter this space with unique products that have the potential for undisputed product leadership to drive revenue growth**

# KORA Market Potential



## US

- KORA market launch: **2021**
- Total EUS biopsy procedures ~357,000 (2021);  
KORA market potential >**\$120 million**
- Total procedures expected to reach 422,000 (2026);  
KORA market potential >**\$140 million**



## ROW

- KORA market launch: **2023**
- Total EUS biopsy procedures ~811,000 (2023);  
KORA market potential >**\$190 million**
- Total procedures expected to reach 897,000 (2026);  
KORA market potential >**\$215 million**

# Market Moving Towards Precision Medicine

- For improved, personalized tumor diagnosis and treatment
- Based on molecular profiling; analyzing patient's DNA, RNA, and protein in cancer cells
- Requires **high quality tissue sample**
- Matches patient with the best treatment



Limaca's KORA GI will advance precision medicine and enable **improved diagnosis and better prognosis.**

# Experienced Team



## **ASSAF KLEIN, CEO**

17 years' experience in medical device companies, including managerial and R&D positions; former CEO, MediValve; MBA, Bar-Ilan University; B.Sc., mechanical engineering, Technion Israel Institute of Technology, Israel.



## **IYAD KHAMAYSI, MD, FOUNDER & MEDICAL DIRECTOR**

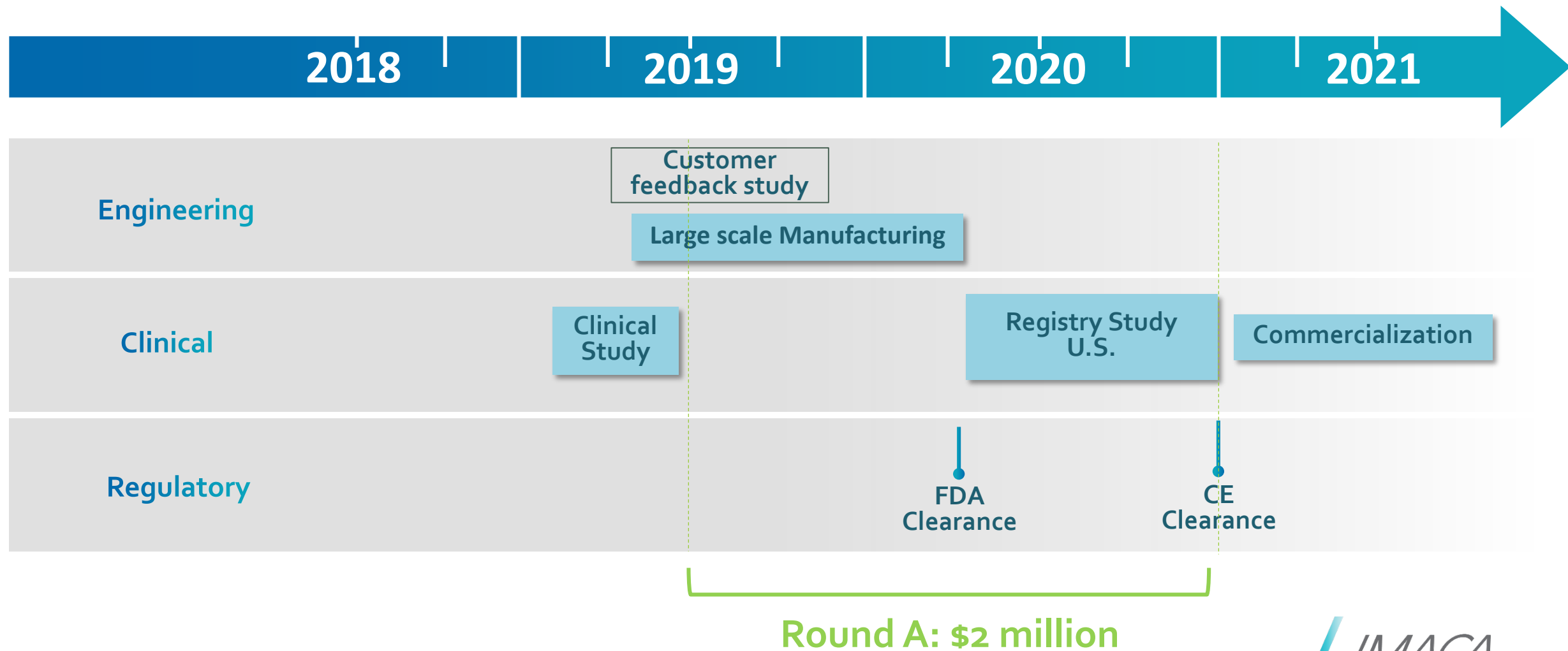
Director, Invasive Endoscopy Unit, Department of Gastroenterology and Hepatology, Rambam Health Care, Israel; entrepreneur and inventor.



## **CARL RICKENBAUGH, CHAIRMAN OF THE BOARD**

President, First Keel Consulting; former Management Board Member and Vice President of New Business Development, Bard Peripheral Vascular & Biopsy (13 years); plus commercial leadership in sales, marketing and product development roles at Abbott Laboratories (13 years).

# Timeline and Milestones



Round A: \$2 million

# Fundraising

Limaca seeks funds to complete

- FDA 510(k) clearance and CE Mark approval
- Production scale-up
- Perform U.S. Registry Study



# Thank You



Assaf Klein, CEO

Carl Rickenbaugh, Chairman

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