The Next Revolution in Endoscopic Ultrasound Guided Biopsy Products

Company Presentation
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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:** Initiated FIH multi-center study in Israel
- **Strong team:** Led by three highly accomplished executives with medical endoscopic, medical device engineering, and biopsy medtech expertise
- **Investors:** [trendlines]

Limaca’s groundbreaking biopsy product will advance precision medicine and enable improved diagnosis and prognosis.
KORA - Revolutionizing US Guided Endoscopic Biopsy

KORA obtains higher quality core tissue for

- superior histopathologic analysis
- improved diagnostic accuracy
- better clinical outcomes
Limaca’s Initial Focus: Pancreatic Tumors

- **55,000 Americans** will be diagnosed with pancreatic cancer this year
- ~9% survival rate
- Every pancreatic tumor is different, requiring specific diagnosis

Future markets in Limaca’s pipeline include Liver and Lung cancer

Sources:
- Pancreatic Cancer Network
- American Cancer Society
Initiated First-in-Human Clinical Study

- Started: May 2019
- Multi-center study in 2 leading centers in Israel
- Comparing to existing EUS fine needle biopsy (FNB)
- Objective: to assess safety, usability, and performance

Prof Iyad Khamaysi using Limaca’s KORA-GI in first-in-human trial at RAMBAM Medical Centre, Haifa, Israel
Background: Endoscopic Ultrasound Tissue Acquisition

- Used for **diagnostic** and **staging** of evaluation of benign and malignant diseases of GI tract and of adjacent organs
- A nonsurgical, minimally invasive procedure which combines
  - Imaging ultrasound during endoscopic procedure
  - Thin, hollow needle inserted into mass for tissue biopsy followed by cytological/histological examination
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
- Additional stabs and time to reach the target tissue
- Frustrated gastroenterologist
- Of 10 biopsies, 2 to 3 will fail
- Patients need to come back for repeat procedures
- 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 Histology Results
Superior sampling v. today’s best performing manual product

Study Device: **KORA- GI**  
3 stabs only

Control Device: **SharkCore**  
35 stabs

Better tissue acquisition  
Less blood contamination

Blood contamination area

Much more blood contamination
Excellent Precision; No Residual Deformity

Comparative accuracy between KORA-GI and Leading FNB FIH Clinical Study 2nd Patient

- KORA GI is positioned perfectly aligned at the end of procedure
  - No deviation from alignment due to unique super elastic characteristics of needle design and material

- EUS guided FNBs has about 20mm deviation from aligned stab
  - Needle is made from stiff material that will not return to its straight condition after advancement through the scope
Comparative echogenicity between KORA GI and Leading EUS-FNB

- **KORA-GI**’s unique needle surface finish characteristic leads to significant superior visualization that contributes to superior precision and clinical outcomes.

- **SharkCore** echogenic surface finish is applied only at the distal tip of the needle, in addition, the bending of the needle takes the needle out of the echo plane. Both lead to inferior visibility and stabbing accuracy.
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 achieve 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

- Filed PCT patent application
- 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

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).
Funding and Milestones

2018 2019 2020 2021

Engineering
- Customer feedback study
- Large scale Manufacturing

Clinical
- Clinical Study
- Registry Study U.S.
- Commercialization

Regulatory
- FDA Clearance
- CE Clearance

Round A
Fundraising

Limaca seeks funding to complete

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

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