

# Colon 3D Imaging Capsule

CORPORATE PRESENTATION  
JANUARY 2019



[www.check-cap.com](http://www.check-cap.com) • Ticker: CHEK (NASDAQ)



# Safe Harbor Statement

## Forward-Looking Statements

This presentation contains forward-looking statements about our expectations, beliefs or intentions regarding, among other things, our ongoing and planned product development and clinical trials; the timing of, and our ability to make, regulatory filings and obtain and maintain regulatory approvals for our product candidates; our intellectual property position; the degree of clinical utility of our products, particularly in specific patient populations; our ability to develop commercial functions; expectations regarding product launch and revenue; our results of operations, cash needs; our financial condition, liquidity, prospects, growth and strategies; the industry in which we operate; and the trends that may affect the industry or us. In addition, from time to time, we or our representatives have made or may make forward-looking statements, orally or in writing. Forward-looking statements can be identified by the use of forward-looking words such as "believe," "expect," "intend," "plan," "may," "should" or "anticipate" or their negatives or other variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical or current matters. These forward-looking statements may be included in, but are not limited to, this presentation, various filings made by us with the SEC, press releases or oral statements made by or with the approval of one of our authorized executive officers. Forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements.

Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including, but not limited to, the factors summarized below. These factors include, but are not limited to, the following: our history of losses and needs for additional capital to fund our operations; our ability to continue as a going concern; our inability to obtain additional capital on acceptable terms, or at all; the initiation, timing, progress and results of our clinical trials and other product development efforts; our reliance on one product or product line; the clinical development, commercialization and market acceptance of our C-scan system; our ability to receive de novo classification and other regulatory approvals for our C-scan system; our ability to successfully complete clinical trials; our reliance on single-source suppliers; our reliance on third parties; our ability to establish and maintain strategic partnerships and other corporate collaborations; our ability to achieve reimbursement and coverage from government and private third-party payors; the implementation of our business model and strategic plans for our business; the scope of protection we are able to establish and maintain for intellectual property rights covering our C-scan system and our ability to operate our business without infringing the intellectual property rights of others; competitive companies, technologies and our industry; and statements as to the impact of the political and security situation in Israel on our business. More detailed information about the risks and uncertainties affecting Check-Cap is contained under the heading "Risk Factors" included in Check-Cap's most recent Annual Report on Form 20-F filed with the SEC on April 4, 2018, and in other filings that Check-Cap has made and may make with the SEC in the future.

These statements are only current predictions and are subject to known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. Given these uncertainties, you should not rely upon forward-looking statements as predictions of future events.

All forward-looking statements attributable to us or persons acting on our behalf included in, but not limited to, this presentation speak only as of the date hereof and are expressly qualified in their entirety by the foregoing. We undertake no obligations to update or revise forward-looking statements to reflect events or circumstances that arise after the date made or to reflect the occurrence of unanticipated events. In evaluating forward-looking statements, you should consider these risks and uncertainties.

This presentation shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

The presentation contains information about an investigation-stage medical device product under development, which has not yet been approved by the FDA for commercial distribution in the United States. All representations in this presentation are based upon investigations in certain clinical and other research, but which accordingly should not be construed as general claims for the safety or efficacy of the products when used by patients.

# Our Mission

To prevent colon cancer  
through the first and only  
preparation-free Capsule based screening method  
for precancerous polyp detection



# Check-Cap at a Glance

**Advancing C-Scan® -  
a patient-friendly  
Colon 3D Imaging system**



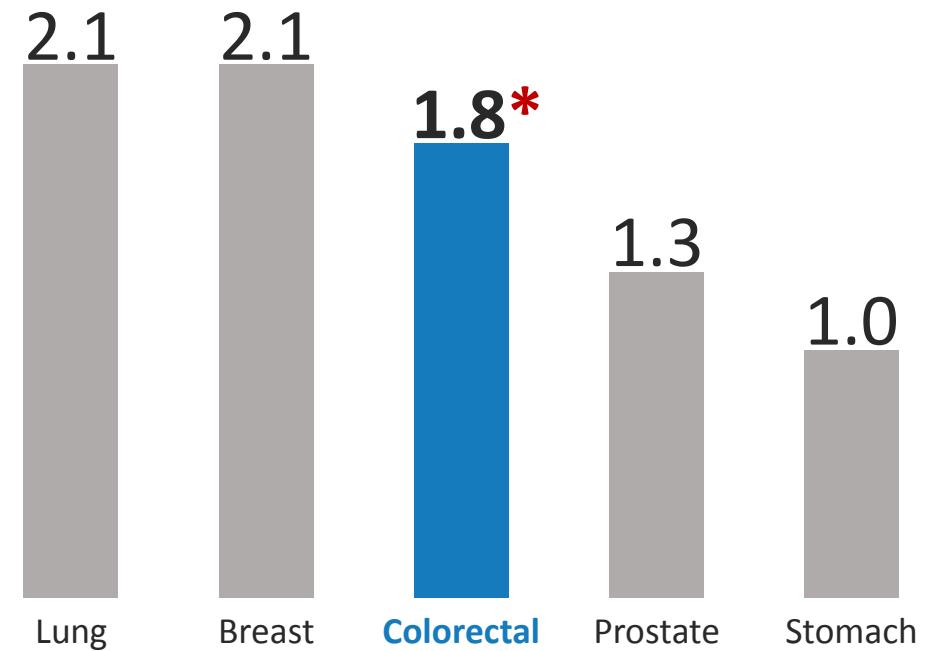
- NASDAQ: CHEK
- Headquarters: Isfiya, Israel
- Market cap: \$12.8M\*
- Cash and equivalents: \$17.6M\*\*
- Received CE Mark approval
- Approved for sale in Israel

# CRC is the Third Most Commonly Diagnosed Cancer

- **1.8M new cases and 881,000 deaths worldwide.<sup>1</sup>**  
**\*60% increase expected by 2030<sup>2</sup>**
- Only 60% of U.S. target population in 2015 adheres to colonoscopy<sup>4</sup>
- Represents an economic burden of **\$ ~14B** in 2010 the U.S. alone<sup>5</sup>

## Most Commonly Diagnosed Cancers

Worldwide estimated figures, in millions, 2018



Sources:

1 [http://gco.iarc.fr/today/data/factsheets/cancers/10\\_8\\_9-Colorectum-fact-sheet.pdf](http://gco.iarc.fr/today/data/factsheets/cancers/10_8_9-Colorectum-fact-sheet.pdf)

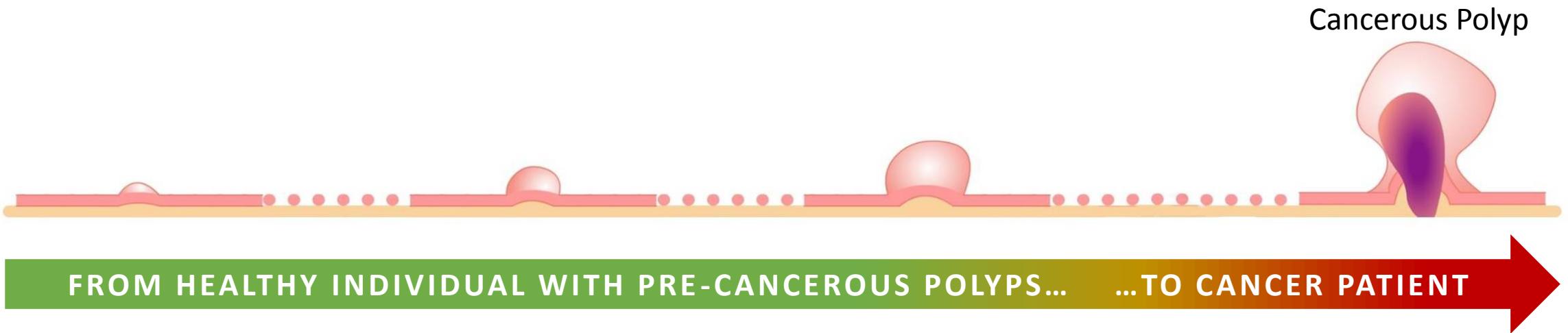
2 <https://gut.bmjjournals.org/content/66/4/683>

3 <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/colorectal-cancer-facts-and-figures/colorectal-cancer-facts-and-figures-2017-2019.pdf>

4 Target population relates to adults 50 years and older and adherence to colonoscopy relates to having either a sigmoidoscopy in the past 5 years or colonoscopy in the past 10 years.

5 <https://costprojections.cancer.gov/expenditures.html>

# But Is Also Highly Preventable With Screening



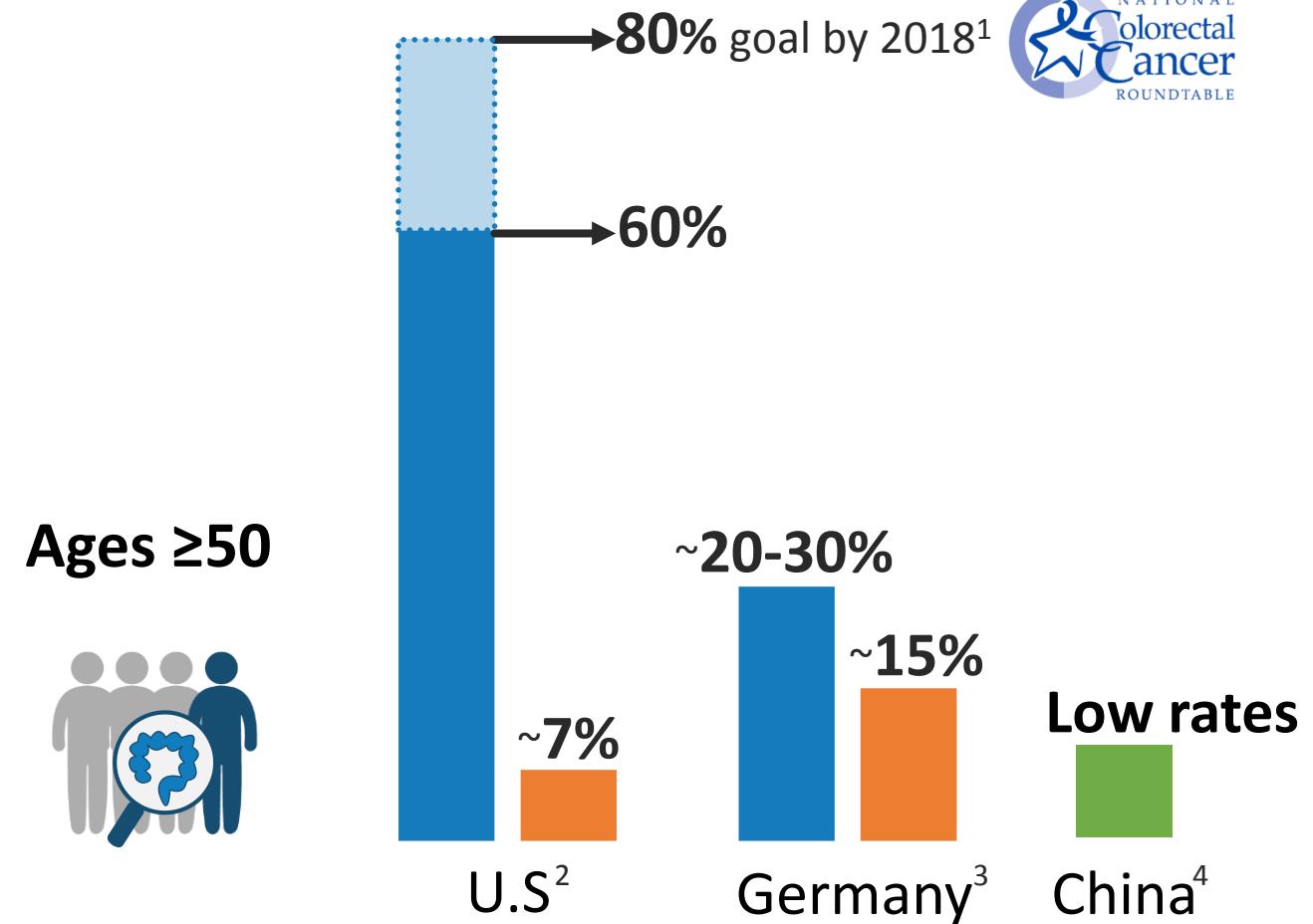
~10 Year Prevention Opportunity

# Global Screening Rates Remain Low

	Colonoscopy	<b>88-98 (%)*</b>
	FIT	<b>32-53 (%)*</b>
	FOBT	<b>9-24 (%)*</b>

\*Sensitivity for pre-cancerous polyps.

Source:  
Schreuders EH, et al. Gut. 2015;0:1–13. doi:10.1136/gutjnl-2014-309086.



## Sources:

1. 2018 goal, ages 50-75 years, [https://www.cdc.gov/cancer/dcpc/research/articles/crc\\_screening\\_model.htm](https://www.cdc.gov/cancer/dcpc/research/articles/crc_screening_model.htm)
2. Relates to ages 50 years and older, as of 2015. For colonoscopy, this includes adults that had a colonoscopy in the past 10 years or sigmoidoscopy in the past 5 years. For FIT this includes adults that had FIT or FOBT in the past year.  
<https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/colorectal-cancer-facts-and-figures/colorectal-cancer-facts-and-figures-2017-2019.pdf>
3. For FIT this relates to 50-54 year olds testing for fecal blood in 2014. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5341111/>, <http://www.cancer-days.eu/res/file/presentations/2017/04-state-of-the-art-04b-seufferlein.pdf>
4. No national program data available. Company estimate (of low screening rate) based on third-party sources.

# Barriers to Colonoscopy Screening in U.S.



*"What do you feel is the most troubling part of colon testing?"*

32%



21%



15%



13%



11%



8%



Laxative preparation

Insertion of endoscope

Fasting requirements

Concern over pain

Embarrassment

Other reasons

# CRC Screening Market Opportunity

Screening Population\*  Market Opportunity†

U.S            89M            \$5.34B

EU            220M            \$13.20B

China            348M            \$20.88B

- American Cancer Society (ACS) concluded that new cases of CRC are increasing among younger adults,  
**from 6% in 1990 to 11% in 2013<sup>1</sup>** 
- In 2018, the ACS announced revised guidelines recommending average risk population **to begin screening at age of 45** instead of 50<sup>2</sup>

Sources:

1 <https://www.ccalliance.org/colorectal-cancer-information/statistics-risk-factors>

2 <https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/acs-recommendations.html>

\*Population age groups 50-74. United Nations DESA/ Population Division – World Population Prospects 2017 (U.S., China and Europe).

†For average risk patients, aged 50-75, screened once every 10 years according to ACS' guidelines, at average estimated C-Scan procedure cost of \$600.



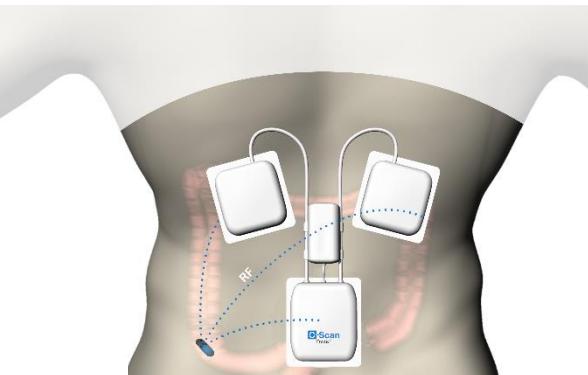
# Our Solution: C-Scan® Preparation-Free Colon Screening

## C-Scan® Cap

- The *first and only* preparation-free ingestible scanning capsule
- Detects precancerous polyps
- Generates **Imaging** and **Motility** Data



## C-Scan® Track



Biocompatible patch worn on patient's back for **Capsule Control, Tracking, and Data Recording**

## C-Scan® View



Images for illustration only.

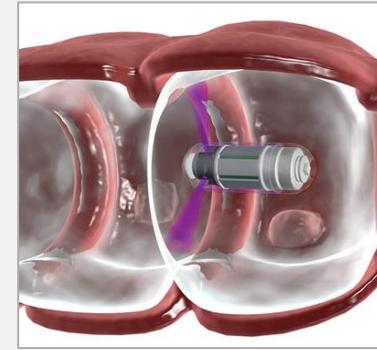


The C-Scan® System is not available for sale or clinical use in the U.S.

# C-Scan®: Preparation-Free Colon Screening

## Disruptive Imaging Technology

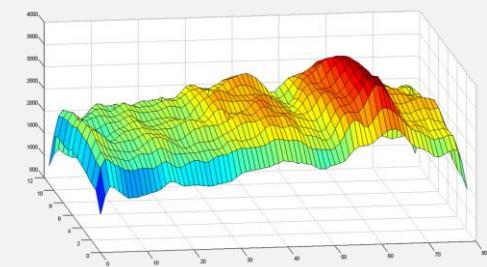
As the capsule moves naturally,  
it scans the inner lining of the colon  
in a 360-degree arc, scanning only when in motion



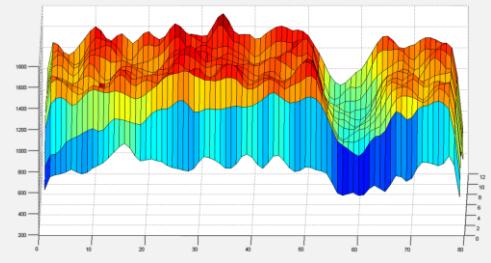
*Capsule scanning over a polyp*

## Exclusive Motility Analysis

Capsule motility is continuously tracked and recorded



*Compton Back-scattering*

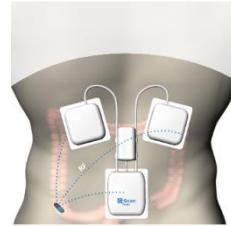


*X-Ray Fluorescence*

# Autonomous, Prep-Free Procedure Can Increase Adherence

## STEP 1: INGESTION

- Patch attached to patient's back
- Capsule ingested -



**NO laxatives**  
**NO boosters**  
**NO sedation**



## STEP 2: NORMAL DAILY ROUTINE

- No special diet
- Contrast agent + Fibers (1 tablespoon) with each meal

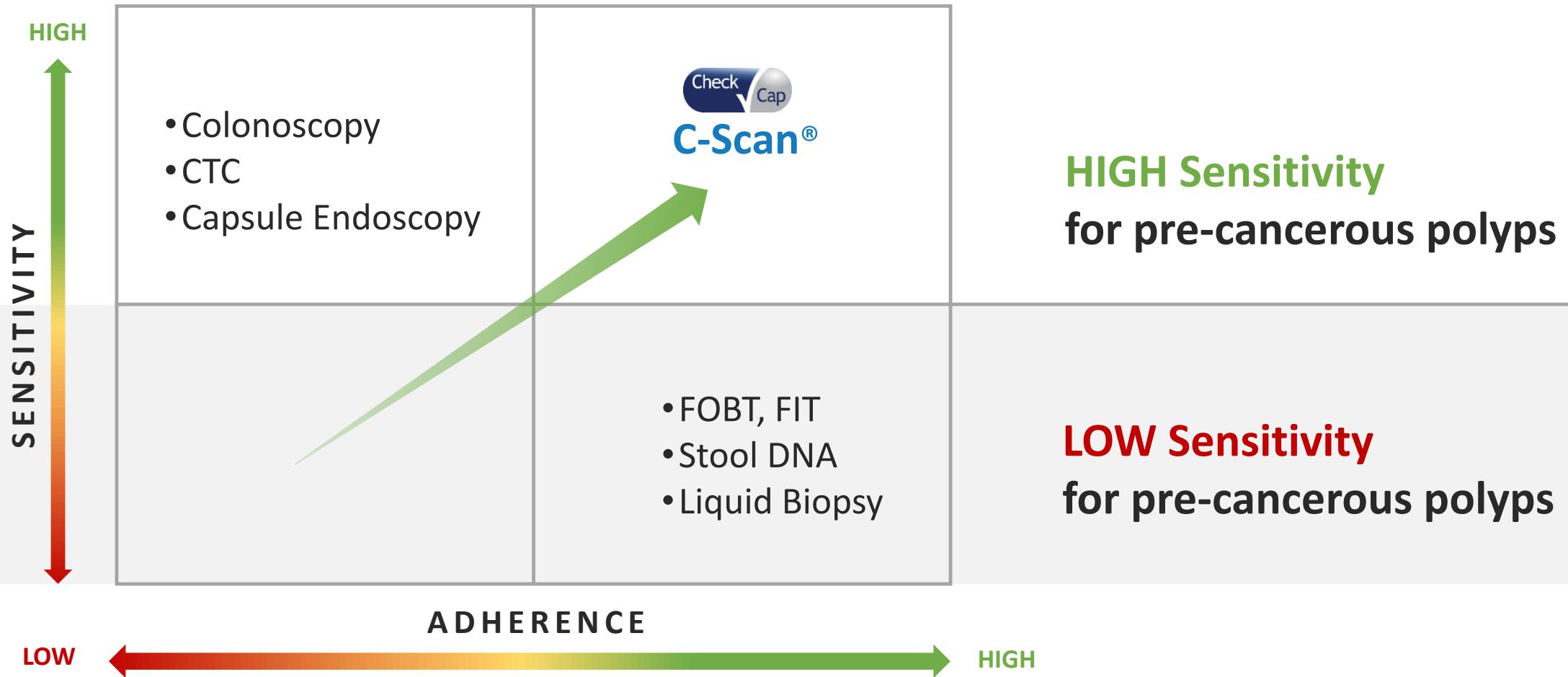


## STEP 3: EXCRETION

- Single use capsule
- Patient is notified once capsule is excreted naturally
- Data is downloaded from patch to workstation for analysis



# C-Scan<sup>®</sup>: Increasing Adherence, detecting pre-cancerous polyps



Sources: AGA Institute Guidelines for the Early Detection of Colorectal Cancer and Adenomatous Polyps.  
American Cancer Society. Colorectal Cancer Facts & Figures 2017–2019. Atlanta: American Cancer Society; 2017 USPSTF. JAMA. 2016;315(23):2564–2575. doi:10.1001/jama.2016.5989.

# C-Scan® Advantages



## PHYSICIAN

- ✓ **Proposed Solution** for patients refusing or cannot undergo colonoscopy
- ✓ **Analysis anywhere** – Portal based analysis suite
- ✓ **Augmented** polyp removal



## HOSPITAL

- ✓ **NO** need for anesthesia
- ✓ **NO** operating room
- ✓ **Minimal** staff involved



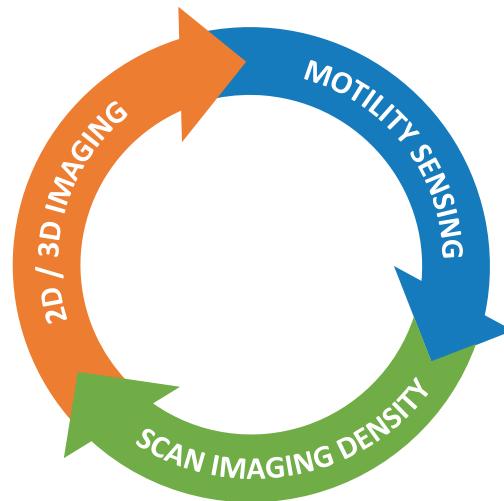
## PAYER

- ✓ **Reduces** CRC incidents and mortality
- ✓ **Saves** treatment cost

# C-Scan® : Positive Interim Results - Ongoing Post-CE Approval Study

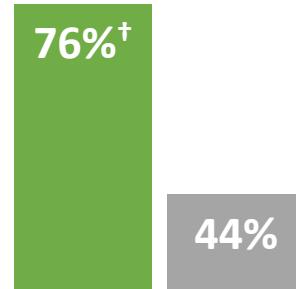
**Objective:** Evaluate safety and clinical performance

*Enhanced performance*

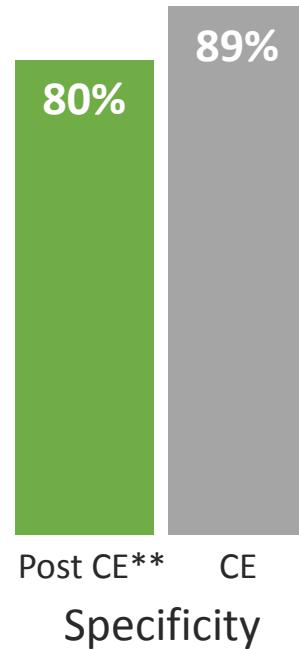


**Final study results expected in Q2 2019**

*Interim Post CE Results  
vs. Final CE Results\**



Post CE\*\*      CE  
Sensitivity



Post CE\*\*      CE  
Specificity

\* Post CE interim results (September 2018) using version 3 of the C-Scan system compared to final results (September 2017) of earlier version of the C-Scan system used in support of CE submission

\*\* Using the full patient population with a gender-based analysis.

<sup>†</sup>P=0.0038; interim data.

# Compelling Clinical Value: Strong Support From KOLs

*"I believe that the diagnostic yield of the C-Scan® system, based on the combined diagnostic test, including scan imaging and gut motility, can be accepted as an important CRC screening tool following results' validation on a larger data base."*

## Professor Jan Tack

Professor of Medicine, Translational Research Center for Gastrointestinal Disorders (TARGID), University of Leuven, Belgium. Department of Clinical and Experimental Medicine, University of Leuven and Head of Clinic, University Hospital Gasthuisberg, Department of Gastroenterology

*"C-Scan® is a swallow-and-forget breakthrough device that can change the history of colon cancer screening and prevention."*

## Professor Nadir Arber

Professor of Internal Medicine and Gastroenterology Head, Health Promotion Center Head, Integrated Cancer Prevention Center, Tel-Aviv Sourasky Medical Center

*"C-Scan® is a novel approach to improve colon cancer screening that can become an alternative to current screening methods. The device generates 3D colon mapping without the need for bowel preparation through which it eliminates barriers for screening noncompliance and has potential to save people lives."*

## Professor Seth A. Gross

Associate Professor of Medicine at NYU School of Medicine; Gastroenterology Section Chief at Tisch Hospital; Director of Endoscopy at NYU Langone Medical Center

*"The novel data on possible association between intestinal motility and colon polyps may provide new insight into the natural history of CRC. Identifying intestinal motility as a contributing risk factor for CRC has the potential to further improve screening protocols for patients at risk for CRC."*

## Professor Yehuda Ringel

Chief, Division of Gastroenterology and Hepatology at Meir Medical Center, Affiliated with Tel Aviv University and Adjunct Professor of Medicine at the University of North Carolina at Chapel Hill

# Efficient Pathway to Commercialization

- ✓ >300 capsules ingested: no reported SAEs
- ✓ EU - CE mark attained
- ✓ FDA IDE conditional approval granted for U.S. Pilot Study
- ✓ Prominent U.S. hospital to conduct U.S. Pilot Study<sup>1</sup>
- ✓ Israeli Ministry of Health (“AMAR”) approval obtained<sup>2</sup>
- U.S. – Regulatory Pathway ongoing; GE health care as partner
- Continuous discussions with potential strategic partners



GE Healthcare



1. Pending Institutional Review Board (IRB) approval  
2. Subject to AMAR renewal in Feb 2019

# Robust Intellectual Property

Core patents granted in major jurisdictions

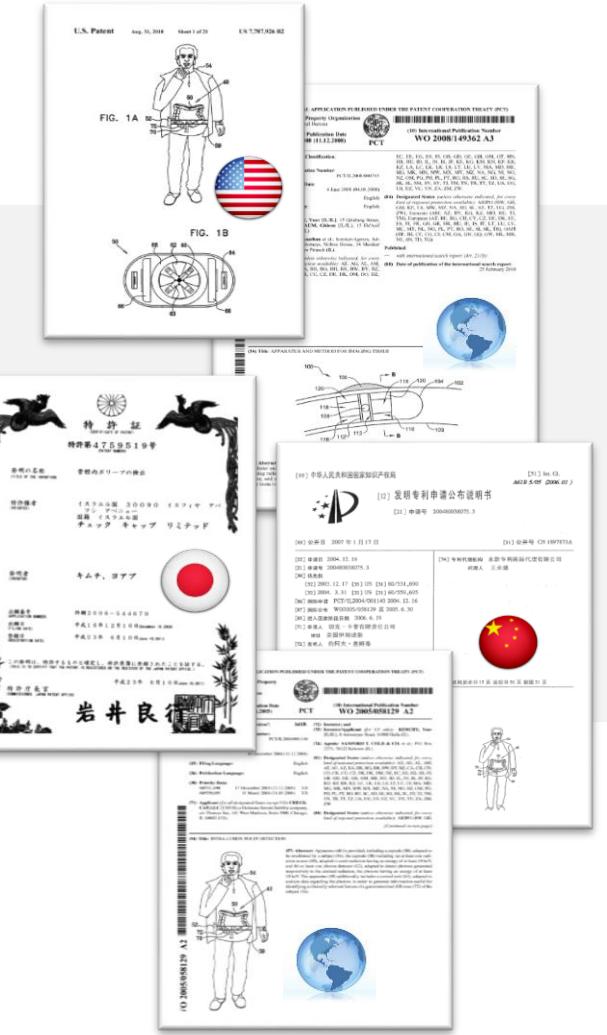
36 Granted

1 Allowed

20 Pending worldwide

Exploring potential new applications for C-Scan®, including:

- Gastrointestinal physiological data analysis
- Localized drug delivery
- Other potential GI tract monitoring capabilities



## EXECUTIVE MANAGEMENT

Alex Ovadia  
CEO



Dr. Yoav Kimchy  
Founder & CTO

Lior Torem  
CFO & VP Operations

Boaz Shpigelman  
VP R&D



## BOARD OF DIRECTORS

Steve Hanley  
Chairman



Dr. Walt Robb\*



Yuval Yanai



Dr. Mary Jo Gorman



XQ Lin

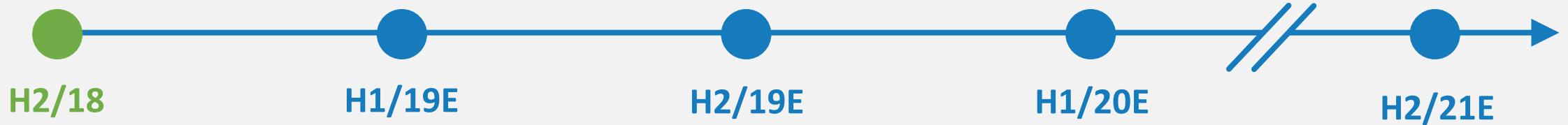


Clara Ezed



Management and Board experienced in medical technology development and commercialization

# Near-Term major Milestones



- |   |  |   |  |                                  |
|---|--|---|--|----------------------------------|
| ✓ Post CE approval study interim results          | • Manufacturing line at GE ready           | • Sales initiation in Israel <sup>2,3,4,5</sup> | • U.S. Pivotal Study initiation <sup>2,3,6</sup> | • File with FDA <sup>2,3,6</sup> |
| ✓ C-Scan® system approved for marketing in Israel | • U.S. Pilot Study initiation <sup>1</sup> | • Sales initiation in EEA <sup>2,3,4</sup>      |  |                                  |
| ✓ IDE conditional approval for U.S Pilot Study    | • Post CE approval study final results     |   |  |                                  |

1. Pending IRB approval

2. Pending strategic partnership.

3. Pending sufficient capital.

4. Pending additional regulatory approval as may be required.

5. Subject to AMAR renewal extension

6. Assuming de novo classification, no PMA and no additional clinical studies required.

# Investment Summary

## Significant unmet need in colorectal cancer (CRC) screening

- ✓ ~**881,000 deaths and ~1.8M new cases** globally in 2018
- ✓ Opportunity to increase worldwide screening rates

## C-Scan®: a potential paradigm shift in CRC screening

- ✓ **Prep-free screening method for precancerous** polyp detection
- ✓ Patient-friendly and addresses legacy aversion to colonoscopy

## Efficient pathway to commercialization

- ✓ **GE as partner**; CE Mark approved; approved for sale in Israel
- ✓ US Pilot Study to commence in H1 2019

## Strong worldwide IP franchise

- ✓ **36 patents granted**, 1 allowed, 20 pending
- ✓ Allows for potential development of new C-Scan® applications

## Experienced leadership team

- ✓ Management experienced in navigating regulatory pathways and product launch/commercialization

# Appendix

# Reimbursement for Screening Methods

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- **Colonoscopy**

U.S

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Medicare	\$1,212 <sup>1</sup>
(Out of pocket private sector	\$2,100 – \$3,764 <sup>2</sup> )

- **Cologuard** (Stool DNA, Exact)

\$509<sup>3</sup>

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Japan

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- **Capsule Endoscopy** (Medtronic)

\$763\*<sup>4</sup>

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\*83,100 JPY in 2014 or \$763US (based on Jan 2, 2019 rates).

Sources:

1. Relates to estimated average cost with biopsies in 2015 <https://link.springer.com/article/10.1007/s00261-015-0538-1>

2. <https://aspe.hhs.gov/system/files/pdf/255906/DHINAdditionalInfor.pdf>, <https://www.bankrate.com/finance/smarter-spending/how-much-does-colonoscopy-cost.aspx>

3. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf>

4. <http://mayafiles.tase.co.il/rpdf/854001-855000/p854945-00.pdf>

# X-ray Exposure Control

