



# Check-Cap

*Creating a new standard of colon 3D imagery*



**May 2014**

**Non Confidential**

# Company Overview



**Founded - 2005**

**Corporate Headquarters - Carmel, Israel**

**Employees - 35**

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## **Investors – Overall \$25m Raised**

through March 31<sup>st</sup> 2014:

GE Ventures, Pontifax Ventures,  
Jacobs Investment (Qualcomm),  
Counterpoint, Docor, BXR Partners,  
Emigrant Saving Bank,  
Biomedix (BMDX:TASE) & more.

**Cash \$3.2m as of May 2014**

**Current Burn Rate - ~ \$400k**

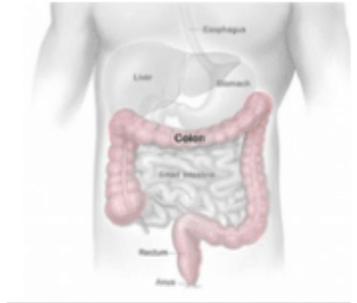
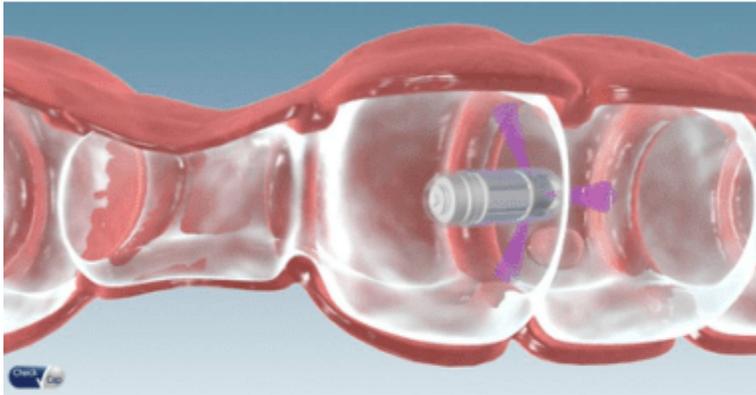
**Target Bridge - \$6-8m**

**Insider Participation - \$3-4m**

**Most Recent Valuation (2012) - \$64m**



# A **patient friendly** screening method



 First **imaging capsule** for  
Colorectal Cancer **screening (CRC)**

 **No bowel cleansing** required

 Designed for **increased compliance**



# Check-Cap **Our vision**



To become the leading supplier  
of colon cancer screening technology  
and significantly reduce  
global mortality from CRC.



*“The most preventable, yet **least prevented** cancer.”*

*– Journal of the National Cancer Institute*

1,000,000  
new cases

600,000  
deaths

\$99 Billion  
spent on  
treatment

**Annually, Globally**

Most lives  
could have been  
Saved

# The importance of CRC screening

**Structural Tests** - enable both Polyp Detection and Cancer Prevention

**Stool / Blood Tests** - enable Cancer Detection

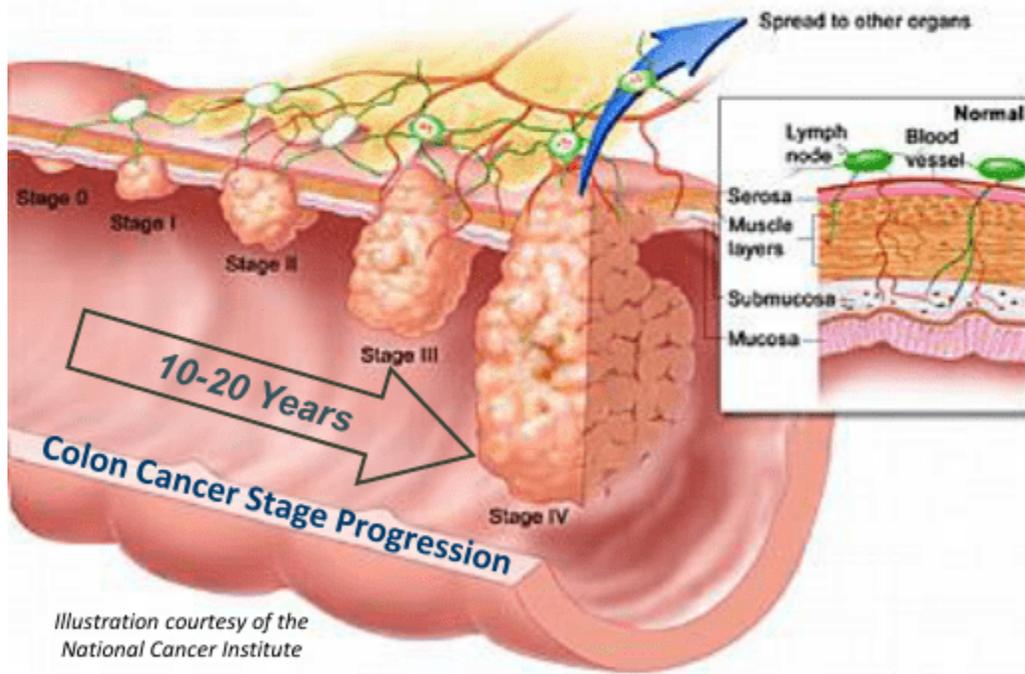


Illustration courtesy of the National Cancer Institute

Highly **Survivable** in **Early stages**

|           |        |
|-----------|--------|
| Stage I   | 93%    |
| Stage II  | 72-85% |
| Stage III | 44-83% |
| Stage IV  | 8%     |

**Testing Compliance Key**

*Less than 50% of the recommended population in the U.S is screened for CRC, while less than 30% is screened in Europe.*

# Compelling Market Size

Target population of **365 million** people aged 50 to 75 in U.S, Europe and Japan.

> 36 million require screening annually.<sup>(1)</sup>

| Population between 50-75 | 2015    | 2016    | 2017    | 2018    | 2019    | 2020    |
|--------------------------|---------|---------|---------|---------|---------|---------|
| USA                      | 89,545  | 90,996  | 92,179  | 93,182  | 94,297  | 95,618  |
| Europe                   | 233,971 | 236,374 | 239,113 | 242,268 | 245,372 | 248,526 |
| Japan                    | 41,397  | 41,071  | 40,889  | 40,843  | 40,814  | 41,002  |
| TOTAL                    | 364,913 | 368,441 | 372,181 | 376,293 | 380,483 | 385,147 |



> **\$18 billion total market opportunity per annum**<sup>(2)</sup>

(1) Assumes one screening for members of the target population every 10 years.

(2) Based on an average selling price of \$500.

# Attractive Market Opportunity

## *Poorly Addressed by Current Methods*

- Current technologies may compromise accuracy or patient safety and comfort
- Colonoscopies involve significant risks and require aggressive bowel cleansing
- Patient compliance levels far below those recommended by physician societies



## *Check-Cap Offers a Differentiated Solution*

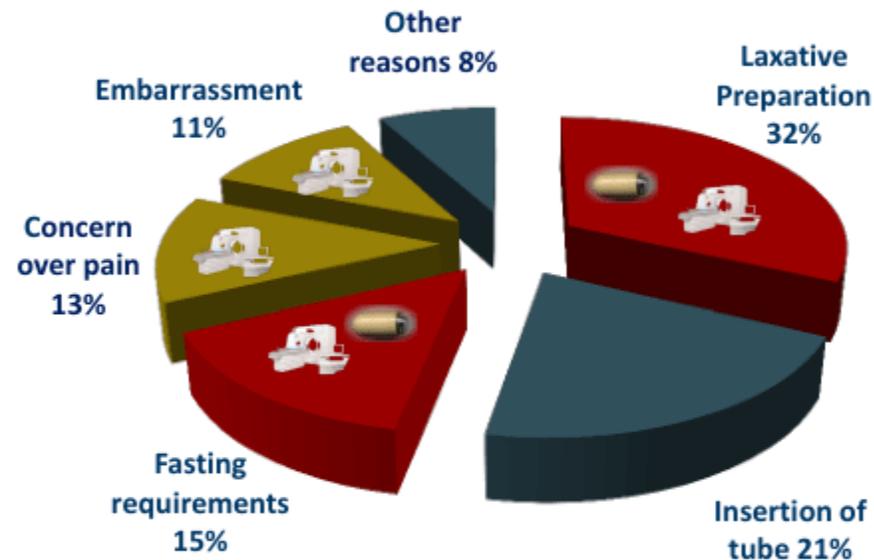
- **Does not require uncomfortable bowel cleansing** necessary for other methods
- Innovative and proprietary technology platform avoids traditional issues
- Designed to be attractive to physicians and patients, increasing patient compliance

# Reasons for Avoiding Existing CRC Screening Procedures

Computed Tomographic Colonography



Camera pill



**Check-Cap imaging capsule addresses all these concerns ✓**

Source: Mayo Clinic Proc. 2007;82(6):666-671. Figure 1, Most troubling part of colon testing. Responses to the question, "What do you feel is the most troublesome part of colon testing?"



# Current Primary Modalities

\* Detection of polyps > 50%  
(Cancer Prevention vs Detection)

|               |   | Safety                           | Comfort                            | Pre-Cancerous Efficacy*                                | Key Competitors  |
|---------------|---|----------------------------------|------------------------------------|--|--|
| Structural    |  Colonoscopy   | X Perforation<br>Cross Infection | X bowel cleansing<br>Embarrassment | ✓ Sensitivity - 95%<br>Specificity - 95%               | <b>OLYMPUS</b> <b>PENTAX</b>   |
|               |  Computed Tomographic Colonography (CTC)               | ✓ Insufflation<br>Radiation      | X bowel cleansing<br>Pain          | ✓ Sensitivity - 85%<br>Specificity - 95%               |  <b>PHILIPS</b><br><b>SIEMENS</b>           |
|               |  Optic Capsules  | ✓                                | X- bowel cleansing                 | ✓ Sensitivity - 70%<br>Specificity - 85%               | <b>OLYMPUS</b><br>                          |
| Fecal & Blood |  Fecal Occult Blood Test                               | ✓                                | ✓                                  | X Sensitivity - 23%<br>Specificity - 97%               |  <b>Hemocult</b><br>Fecal Occult Blood Test |
|               |  Stool DNA<br><i>In clinical trials</i>              | ✓                                | ✓                                  | X Sensitivity - 42%<br>Specificity - 87%               |   |
|               |  Blood Tests<br><i>In clinical trials</i>            | ✓                                | ✓                                  | X Sensitivity - 50%<br>Specificity - 90%               | epigenomics  |
| 10            |  <b>Imaging Capsule</b><br><i>In clinical trials</i> | ✓                                | ✓                                  | ✓ Target Sensitivity > 80%<br>Target Specificity > 90% |   |

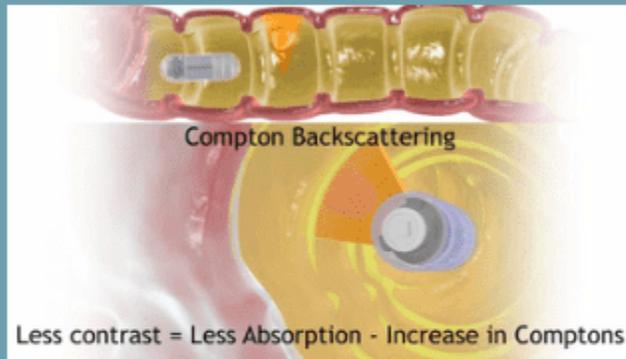


# The Check-Cap Solution

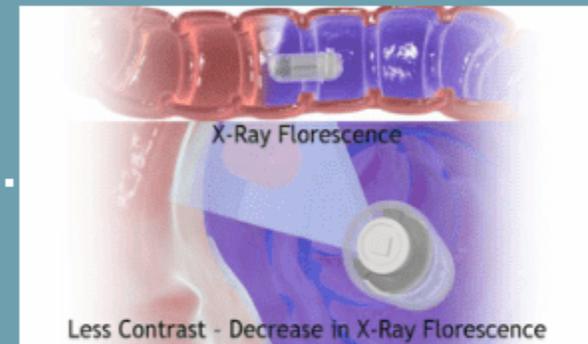


# Check-Cap Imaging Technology

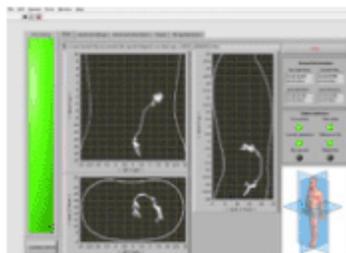
## Back-Scattering



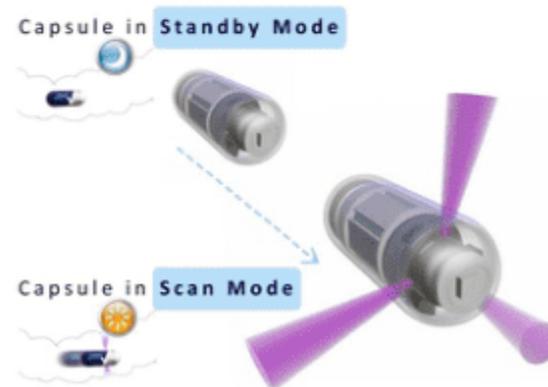
## X-ray Fluorescence



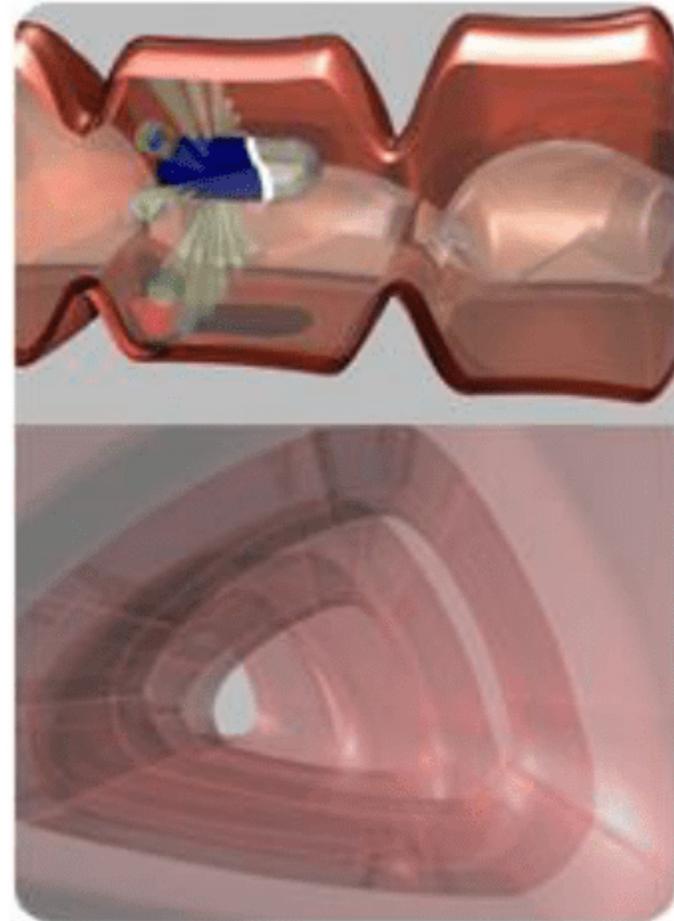
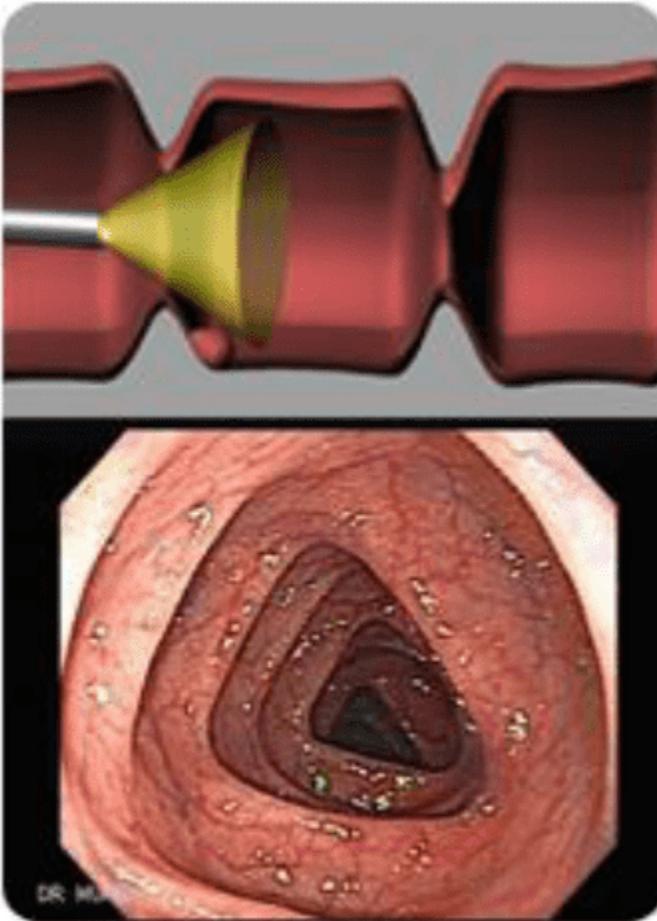
Compton backscattered flux of photons detected by the capsule are attenuated by the colon contents in direct proportion to their distance traveled in the colon contents, as some of the photons are absorbed by the contrast agent



The x-ray Fluorescence flux detected by the capsule's detectors depends monotonically on the distance traveled in the colon contents mixed with the contrast agent



# 3D Capsule Technology vs. Optics



# 3D Image Reconstruction

The screenshot displays the CapScanViewer 10A software interface. At the top, the 'Check Cap' logo is on the left, and the title 'CapScanViewer 10A' is on the right. Below the title bar, a dark blue header contains the text 'STUDY - Nov. 2014 Erasmus MC University Hospital, Rotterdam', 'ID-AB20166585', and 'Dr. Arber'. The main interface is divided into several panels:

- Bookmarks Panel (Left):** A table with columns '#', 'Scan No.', 'Location %', and 'Status'. It contains two rows of data:

| # | Scan No. | Location % | Status |
|---|----------|------------|--------|
| 1 | 4        | 12         | ●      |
| 2 | 8        | 45         | ●      |
- Standart 3D Panel (Center):** Displays a 3D reconstruction of a colon, colored in shades of red and orange. Below it is a 'PreProcessed' panel showing a 3D surface plot of the colon's topography.
- 2D Single Slice Panel (Right):** Shows a 2D cross-section of the colon on a grid. Below it is a '3D Scan Location' panel with a circular navigation icon.
- Navigation and Control Panel (Bottom):** Includes a 'Display options' section with radio buttons for 'trans line', 'Ground Plane', 'measurements', and 'bookmarks'. Below this is a horizontal slider from '0' to '100' with 'oceum' on the left and 'rectum' on the right. At the bottom are 'Previous Scan' and 'Next Scan' buttons.

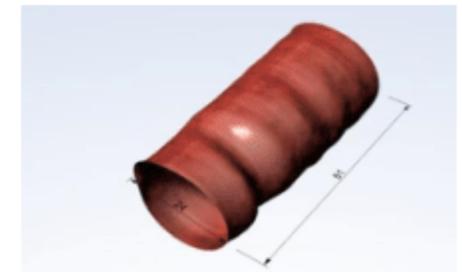
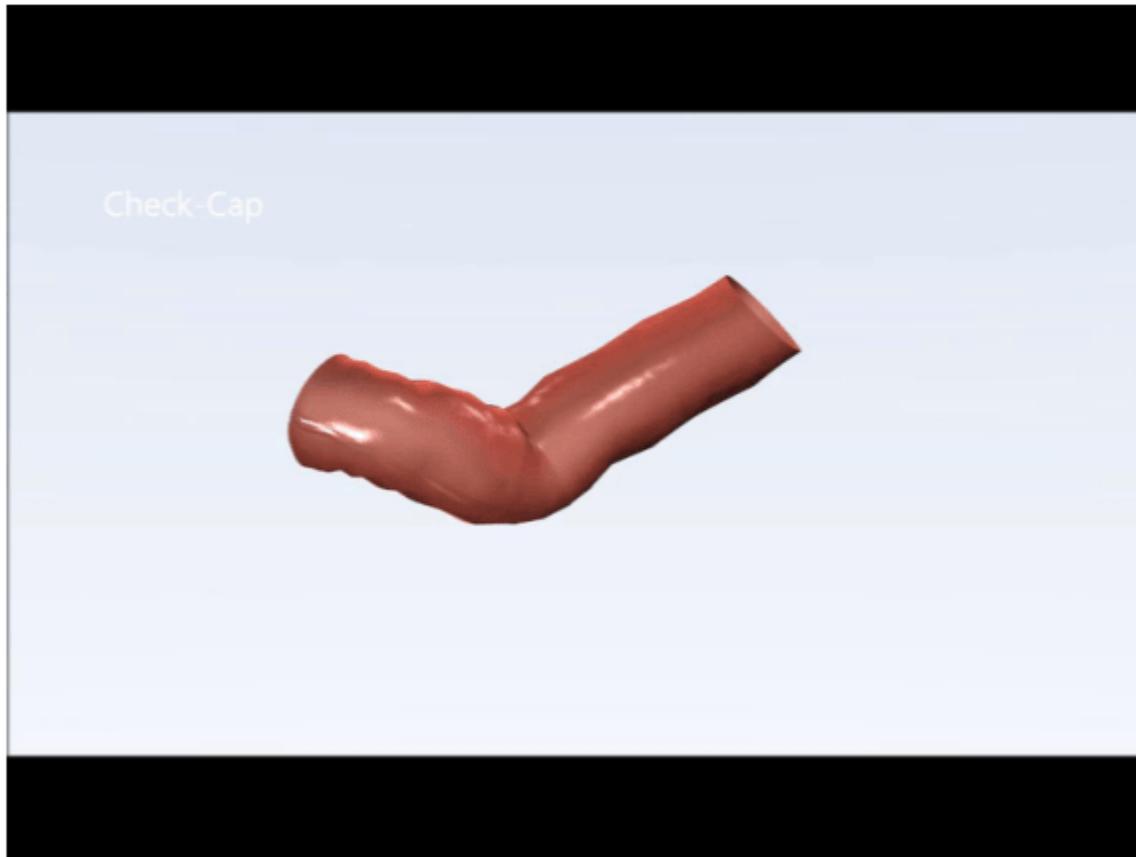
At the bottom of the interface, there are three buttons: 'BROWSE', 'SURF', and 'REPORT'. The 'SURF' button is currently selected.

The data viewer

# Trial Clinical Data

## Reconstruction (3D)

### 3D Reconstructed



# Clinical Proof of Concept

*“The Check-Cap novel imaging technology has been proven to be safe and feasible in our preliminary clinical experience. It has successfully demonstrated imaging of prep-less human colon at ultra-low dose compared to existing X-Ray based modalities. These results underpin the great potential of Check-Cap imaging technology to become a very appealing tool for screening of pre-cancerous polyps and colorectal cancer. Once efficacy is demonstrated, this clearly could make a fantastic impact on screening and consequently on survival rates from this disease”*

→ **Professor Nadir Arber,**  
*Head of Integrated Cancer Prevention Center,  
Tel Aviv Sourasky Medical Center, Israel*

# Clinical proof of concept – Demonstrated Capabilities

- **3D imaging and representation** (with no preparation)
- **Reliable correlation between Compton Backscattering & X-Ray Florescence data**, leading to clinical diameters values
- Automatic **scan in motion** triggered by predefined Activation Algorithm settings
- Colon segment **position data** with high accuracy
- All subjects reported **smooth passage of capsule** along the GI tract
- Acceptable surface imaging using ultra low dose accumulated during procedure
- Contrast material (oral) well tolerated by subjects

## **Quantitative colon surface detection and reconstruction along movement track Results of studies suggest procedure is safe and uneventful**

Results of first studies indicate that the current lower limit for visible feature size is 5~6 mm, and ~10mm polyps should be well within the imaging capability of the Check-Cap capsule.

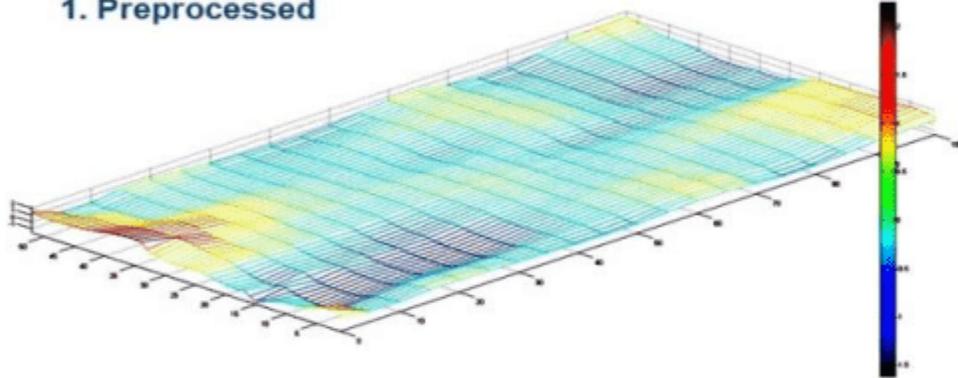
We believe that improvements in hardware and algorithm should enable us to decrease the lower limit of visible feature size to 2 mm, to provide high detection rate for 5 mm polyps & very high detection rate for 10 mm polyps.

# Clinical Trial Data

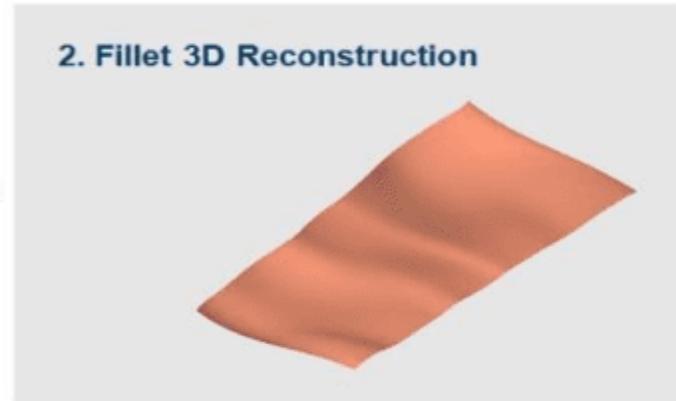
Reconstruction Stages (fused CMT and XRF) - PP100204\_P42-Scan01

## Reconstruction Stages (fused CMT and XRF)

1. Preprocessed



2. Fillet 3D Reconstruction



3. Tubed 3D Reconstruction

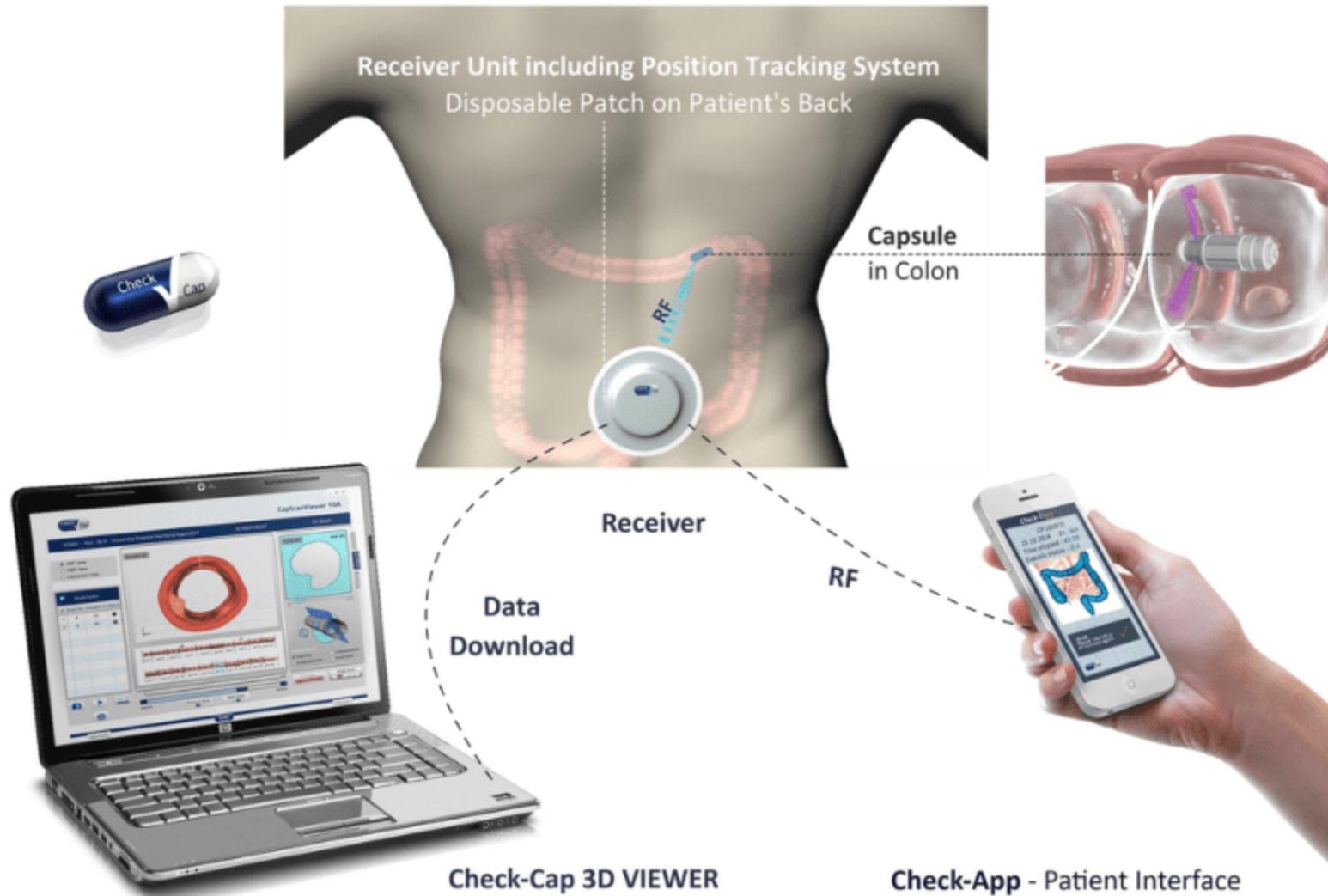


4. Path 3D reform



# Commercializable Tracking System

ELS III – Preliminary concept II



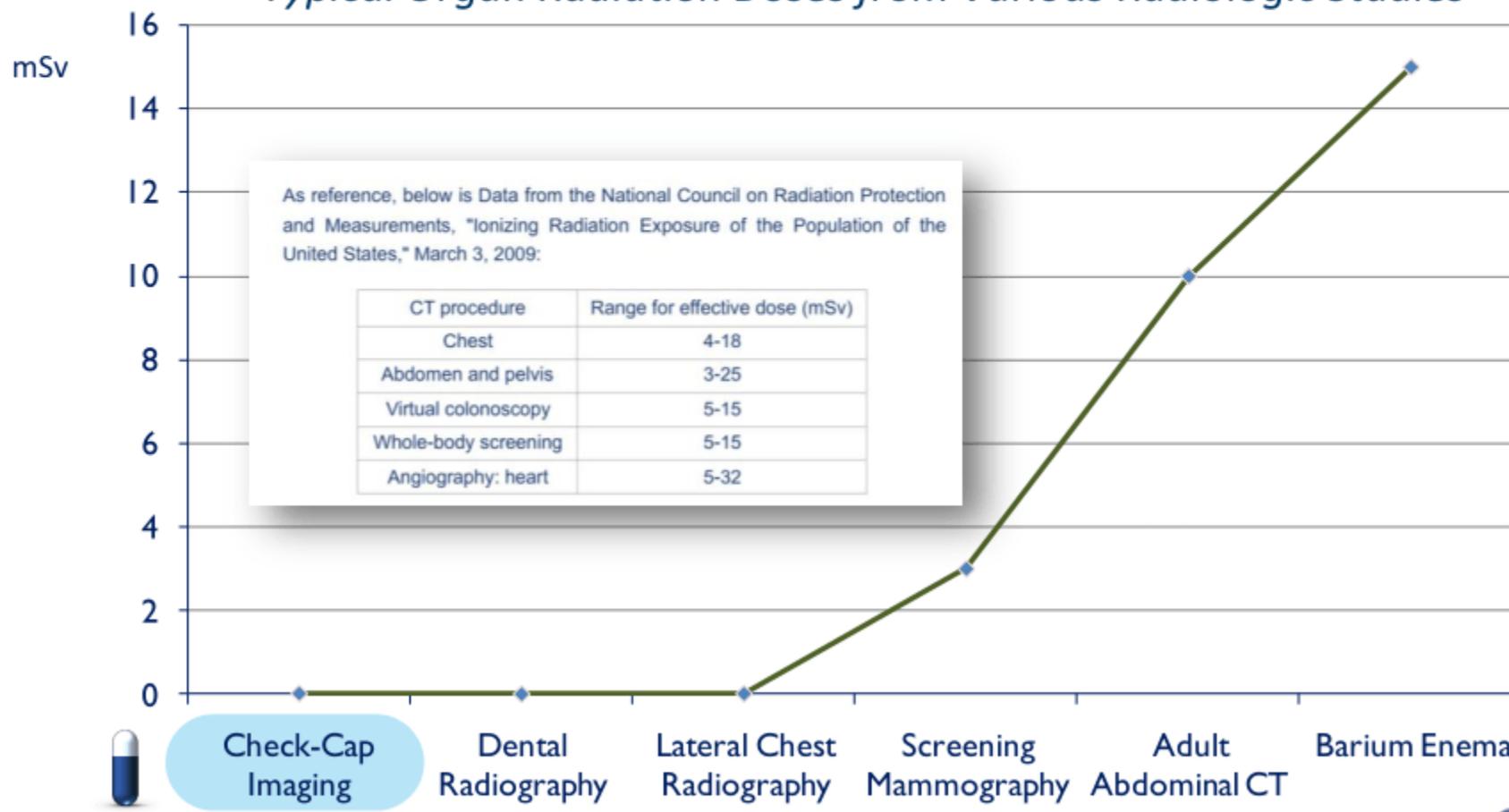
# X-ray radiation control

Low Energy



Low Radiation Exposure

Typical Organ Radiation Doses from Various Radiologic Studies

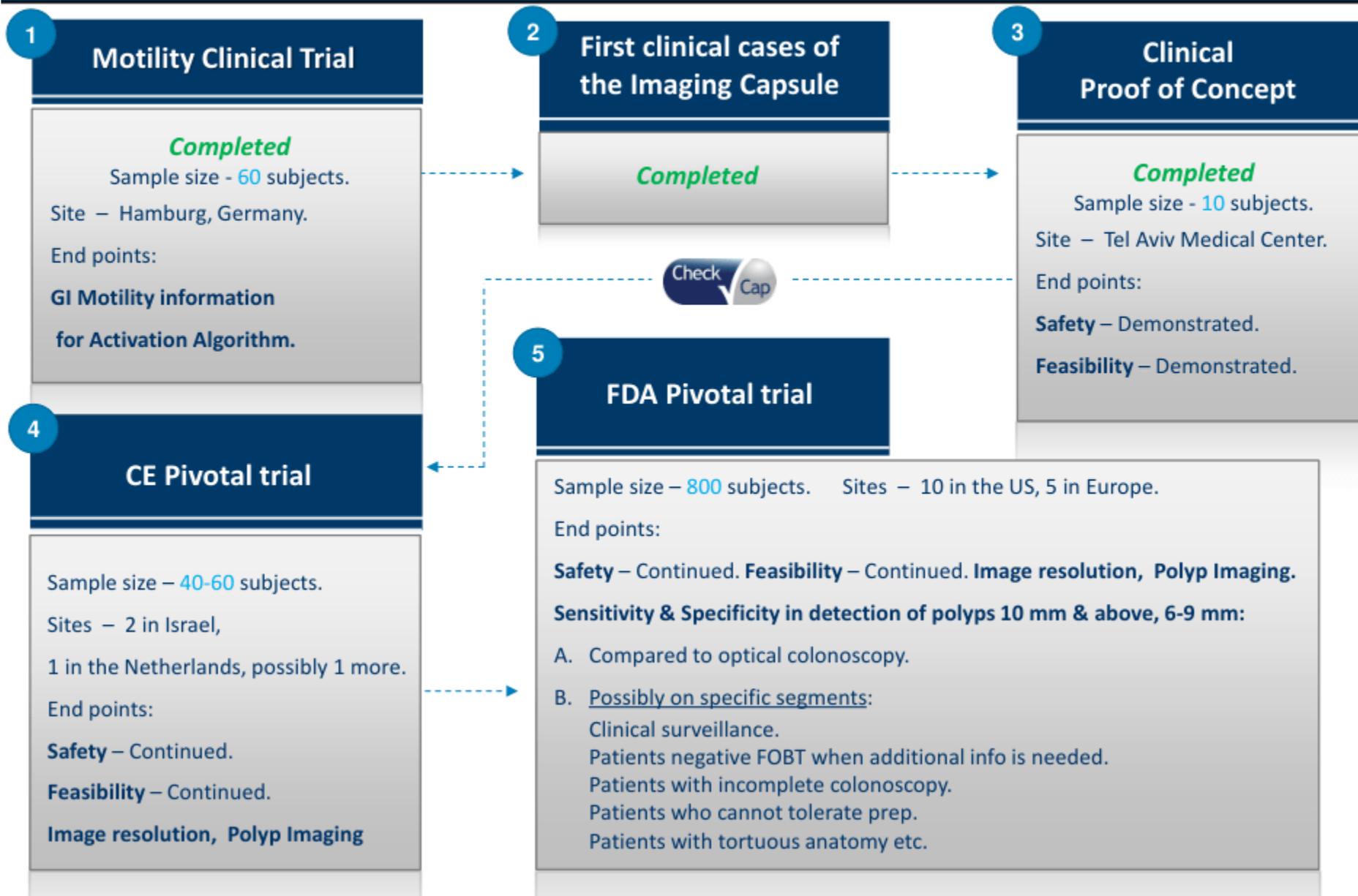


As reference, below is Data from the National Council on Radiation Protection and Measurements, "Ionizing Radiation Exposure of the Population of the United States," March 3, 2009:

| CT procedure         | Range for effective dose (mSv) |
|----------------------|--------------------------------|
| Chest                | 4-18                           |
| Abdomen and pelvis   | 3-25                           |
| Virtual colonoscopy  | 5-15                           |
| Whole-body screening | 5-15                           |
| Angiography: heart   | 5-32                           |



# Clinical Data Generation



# Anticipated Development, Clinical & Financial Roadmap

|   | Q3-Q4 2013  | 2014   | 2015  |
|---|---|--|---|
| <b>Product Development</b>              | Clinical Activation & Clinical Reconstruction algorithm<br>(Design freeze @ Q4/14)                |  | 2nd Gen Capsule Development<br>Inc. cost reduction and optimization   |
| <b>C.E Trials &amp; European Market</b> | <i>TLV Hospital</i><br>Clinical Proof of Concept (5 par.)<br>Clinical AA (10 par.)<br>✓ completed | <i>TLV &amp; Erasmus (NL)</i><br>CE Pivotal (50-60 par.) | Request for CE Mark<br>Post marketing in Europe (200 participants)    |
| <b>US Trials &amp; Regulations</b>      |   | US Protocol, site selection and study design             | Request for FDA trial initiation<br>US Pivotal Trial 800 participants |

# Reimbursement Aspects

## Current Status

### Covered for CRC screening\*:

FOBT

Barium Enema

Flexible Sigmoidoscopy

Optical Colonoscopy

### Not Covered for CRC Screening Yet:

CTC (Covered by some private insurers)

Stool DNA

### Colon - Capsule Endoscopy:

Given's capsule received FDA clearance

Cost effectiveness models have been designed for Europe

SB & ESO capsules are covered

## Our Strategy

- Collect information about expected increase in screening adherence rate (expected increase > 25%)
- Collect information about direct and indirect costs (expected decrease > 15%)
- Emphasized findings are limited to intra-colon only (as opposed to CTC)
- Utilize capsule endoscopy value story to demonstrate cost effectiveness
- Penetrate private insurers first as differentiating service
- Work with ACG, AGA, ACS to achieve reimbursement as quickly as possible

\* All Medicare beneficiaries age 50 and older are covered;

However, when an individual is at high risk, there is no minimum age required to receive a screening colonoscopy or a barium enema rendered in place of that screening colonoscopy.

# Reimbursement Aspects

414 Original article

## Cost-effectiveness of capsule endoscopy in screening for colorectal cancer

**Authors** C. Hassan, A. Zullo, S. Wien, S. Morini  
**Institution** Gastroenterology and Digestive Endoscopy Unit, "Nuovo Regina Margherita" Hospital, Rome, Italy

**submitted** 16 June 2007  
**accepted after revision** 1 January 2008  
**Background and study aims:** Capsule endoscopy (Pillcam Colon) has recently shown acceptable increases in detecting colonic lesions when compared with colonoscopy and capsule endoscopy was \$1616 and \$29244 per life-year saved, respectively. When equal compliance was simulated, the cost

“... until colonoscopy adherence was decreased to 83%, corresponding to a 17% difference in adherence between the two strategies.”

Cost of treating CRC is \$14 billion annually in the US and \$99 billion globally \*

17% increase in adherence = capsule endoscopy more cost effective than screening colonoscopy

# New Health Care Law

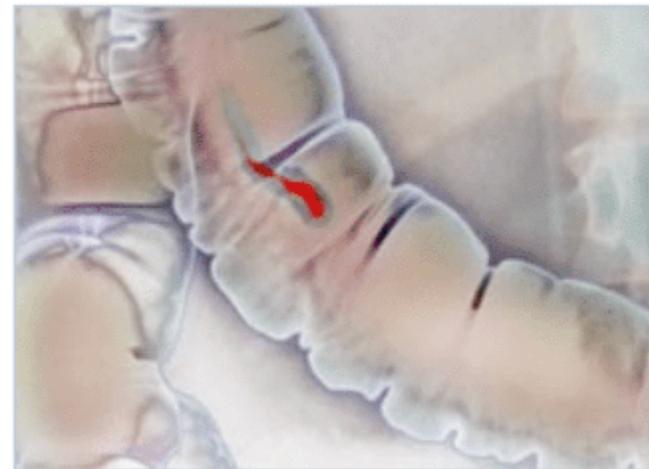
## One benefit of the new health care law: Free colon cancer tests

**1 in 3 U.S. adults have never been screened but will now have coverage for this and other preventive services**

Published: November 07, 2013 10:30 AM

If you've put off getting screened for colon cancer because you didn't have health insurance, there's good news. Under the new health care law, colorectal screening tests are available at no cost to you.

About a third of U.S. adults ages 50 to 75 have never been screened for colon cancer or are not up to date with screening recommendations, according to a [new survey from the Centers for Disease Control and Prevention](#). And more than half of those people had no health insurance. But through the [new health law](#), more Americans will have access to health coverage and preventive services such as colorectal cancer screening tests.



During a colonoscopy, doctors can detect and remove polyps (shown here in red).

# Bridge Financing

- Target raise: US\$6m. Minimum: US\$4m; Maximum: US\$8m
- Terms highly attractive:

|                  |        |
|------------------|--------|
|                  |        |
| Discount         | 25%    |
| Interest         | 5%     |
| Warrant coverage | 100% * |

\* Warrants for four years, at 120% of Offering price

# Intellectual Property

Check-Cap has received patent grants from the U.S. patent office as well as from China, EPO, Japan, Hong Kong and India for the core technology – "Intra lumen polyp detection".

Our granted patents (2010-11) cover an ingestible capsule with a radiation source and radiation detectors that, when used in conjunction with a radio opaque contrast agent, is adapted to detect clinically relevant findings in the colon.



Utilizing X-ray fluorescence and Compton back scatterings, the capsule is able to measure the distance between the capsule and the colon wall and to distinguish between gas and clinically significant findings in the gastrointestinal tract.

# Company Leadership

## Management Team

- **Guy Neev** - **CEO** since March 2008.

14 years of executive management experience.

Chief Executive Officer at Cappella. Business unit manager at Boston Scientific.

- **Alex Ovadia** - **VP of** [REDACTED] since January 2013.

11 years of experience in managing complex [REDACTED] projects at Philips Medical.

10 years of development management positions at Elbit Systems.

- **Yoav Kimchy** - **Founder and CTO** since Feb 2005.

12 years of executive [REDACTED] experience Vice President [REDACTED] at V-Target Ltd.

Director of cardiovascular research at Impulse Dynamics Ltd.

- **Lior Torem** - **CFO** Since Mar 2010.

Strong Chief Financial Officer experience in both private and public companies.

CFO at Tigo Energy Vice President of finance at Actelis Networks Inc

# Scientific Advisors



**Dr. Douglas K. Rex** - Professor of Medicine, Indiana University School of Medicine



**Dr. Perry Pickhardt** - Professor of Medicine, University of Wisconsin Medical School



**Dr. Peter Fitzgerald** - Professor of Cardiology, Stanford University Medical School



**Dr. Nadir Arber** – Professor of Medicine, Tel Aviv Medical Center



**Steve Hanley** - Former President, Covidien's Imaging Solutions unit

\*Partial list

# Summary

- Target Bridge raise: US \$6-8m
- Innovative disruptive technology with clear competitive advantage
- Very attractive market opportunity
- Feasibility & safety clinically proven
- Well defined regulatory pathway
- Core patents granted in all major territories
- Seasoned management & advisory teams
- Leading and committed investors



Thank You

