



# Check-Cap Announces Promising Interim Results from its Ongoing Post-CE Approval Study of C-Scan® System Version 3

**Management to present a corporate overview at the 20th Annual Rodman & Renshaw Global Investment Conference on Wednesday, September 5 at 3:00pm ET**

ISFIYA, Israel, Sept. 4, 2018 /PRNewswire/ -- Check-Cap Ltd. (the "Company" or "Check-Cap") (NASDAQ: CHEK) (NASDAQ: CHEKW) (NASDAQ: CHEKZ), a clinical-stage medical diagnostics company engaged in the development of C-Scan®, an ingestible capsule-based device for preparation-free, colorectal cancer (CRC) screening, today announced the interim results for its post-CE approval study of the C-Scan system Version 3. Data from the multi-center clinical investigation showed promising results for detecting patients with polyps in an un-prepped colon.

The objective of the study is to assess safety and clinical performance of the C-Scan system Version 3 in detecting patients with polyps. In a recent multi-center study on 31 evaluable patients, the C-Scan system Version 3, equipped with improved algorithms, demonstrated a sensitivity (ability to correctly identify polyps) of 76% ( $P=0.0038$ ), with specificity (ability to correctly identify lack of polyps) of 80% for polyp detection, when using the full patient population with a gender-based analysis. Confirmatory colonoscopy and C-Scan system results analysis were performed by independent expert investigators who were blinded to corresponding test's results.

Improvements to the C-Scan system version 3 include better scan imaging density, 2D/3D imaging and a new motility analysis algorithm that was recently tested on two years of continued clinical study data.

Alex Ovadia, CEO of Check-Cap, commented: "We are excited to unveil the multidimensional screening capabilities of the C-Scan system. We believe that the encouraging interim results from our ongoing post CE approval study demonstrate a significant progress in the clinical performance of C-Scan compared with previously communicated CE study results for our patient-friendly, and preparation free colon-cancer screening device. These results were achieved through the continuous improvements in cross-system algorithms, while maintaining C-Scan's strong safety profile. As our post CE approval study continues, with final results planned in 2Q/19 on a more substantial number of patients, we look forward to delivering on our near-term milestones for the remainder of 2018 and forward, including the establishment of the GE manufacturing line and regulatory path in the United States towards the expected initiation of our U.S. pilot trial in 4Q/18."

Professor Nadir Arber, Principal Investigator and Prof. of Internal Medicine and Gastroenterology and Head of the Health Promotion Center and Integrated Cancer Prevention Center at the Tel-Aviv Sourasky Medical Center, stated: "I believe that these interim clinical results demonstrate the C-Scan system's potential to become a meaningful colon cancer prevention device." Prof. Arber continued, "Despite the large body of evidence suggesting that polyp detection and removal can decrease CRC incidence and mortality, the screening adherence among target population is still relatively low. By maintaining this level of clinical performance, C-Scan has the ability to influence screening adherence for those who are unable to undergo a colonoscopy or are unwilling to choose standard CRC screening tests for precancerous polyp detection or stool collection (known to be less effective for precancerous polyp detection) due to common barriers such as unpleasant bowel preparation requirements, invasiveness or stool collection. C-Scan continuously supports the promise to provide a patient-friendly option that could potentially increase CRC screening rates and save lives."

Professor Jan Tack, MD, PhD, Professor of Medicine, Translational Research Center for Gastrointestinal Disorders (TARGID), University of Leuven. Department of Clinical and Experimental Medicine, University of Leuven and Head of Clinic, University Hospital Gasthuisberg, Department of Gastroenterology stated, "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 Yehuda Ringel, MD, 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, stated: "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."

Colorectal cancer is the second leading cause of cancer death in the United States, with an estimated 135,000 diagnoses and 50,000 deaths in 2017. Despite compelling evidence that screening can detect colorectal cancer and precancerous polyps, nearly one-third of the recommended adult population has never been screened. The C-Scan® system is designed to improve patient experience with screening by eliminating many uncomfortable and

invasive requirements of other colon screening procedures, such as bowel preparation, fasting and sedation.

### **Management to Present at the 20th Annual Rodman & Renshaw Global Investment Conference**

Alex Ovadia, Chief Executive Officer of Check-Cap, will provide an overview of the Company's business at the 20th Annual Rodman & Renshaw Global Investment Conference, sponsored by H.C. Wainwright & Co., LLC. The conference is being held on September 4-6, 2018 at the St. Regis New York Hotel in New York City.

If you are an institutional investor, and would like to attend the Company's presentation, please click on the following link ([www.rodmanevents.com](http://www.rodmanevents.com)) to register for the conference.

Event: Check-Cap Presentation

Date: Wednesday, September 5, 2018

Time: 3:00 p.m. EDT

Location: Library, 2nd Floor; St. Regis New York Hotel

To access a live webcast of this presentation, please visit <http://ir.check-cap.com/events-and-presentations>. A replay will be available for 90 days following the presentation.

### **About Check-Cap**

Check-Cap is a clinical-stage medical diagnostics company developing C-Scan®, an ingestible capsule-based device for preparation-free colorectal cancer screening.

Utilizing innovative ultra-low dose X-ray and wireless communication technologies, the capsule generates information on the contours of the inside of the colon as it passes naturally. This information is used to create a 3D map of the colon, which allows physicians to look for polyps and other abnormalities. Designed to improve the patient experience and increase the willingness of individuals to participate in recommended colorectal cancer screening, C-Scan removes many frequently-cited barriers, such as laxative bowel preparation, invasiveness and sedation.

### **Legal Notice Regarding Forward-Looking Statements**

This press release contains "forward-looking statements." Words such as "may," "should," "could," "would," "predicts," "potential," "continue," "expects," "anticipates," "future," "intends," "plans," "believes," "estimates," and similar expressions, as well as statements in future tense, often signify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and may not be accurate indications of when such performance or results will be achieved. Forward-looking statements are based on information that the Company has when those statements are made or management's good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. For a discussion of these and other risks that could cause such differences and that may affect the realization of forward-looking statements, please refer to the "Special Note On Forward-looking Statements" and "Risk Factors" in the Company's Annual Report on Form 20-F and other filings with the Securities and Exchange Commission (SEC). Investors and security holders are urged to read these documents free of charge on the SEC's web site at <http://www.sec.gov>. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

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<https://ir.check-cap.com/2018-09-04-Check-Cap-Announces-Promising-Interim-Results-from-its-Ongoing-Post-CE-Approval-Study-of-C-Scan-R-System-Version-3>