Check-Cap Issues Letter to Shareholders

ISFIYA, Israel, Jan. 27, 2021 /PRNewswire/ -- Check-Cap Ltd. (the "Company" or "Check-Cap") (NASDAQ: CHEK), (NASDAQ: CHEKZ), a clinical stage medical diagnostics company advancing the development of C-Scan®, the first and only patient-friendly preparation-free screening test to detect polyps before they may transform into colorectal cancer, today issued the following letter from its chief executive officer, Alex Ovadia to its shareholders and the investment community:

Dear Check-Cap Shareholders,

I hope this letter finds you and your families healthy and safe during these challenging times. We know that you are enthusiastically following our story and appreciate your patience and support. As we begin 2021 with anticipation, I want to take this opportunity to provide an update on the significant progress Check-Cap has made throughout 2020 with the advancement of our C-Scan technology. C-Scan is a novel patient-friendly capsule-based screening system that does not require laxative bowel preparation prior to procedure, which we believe has the potential to redefine colorectal cancer (CRC) screening and prevention through the detection of precancerous polyps.

I will now walk you through our key updates in more detail:

U.S. Pivotal Study: We continue preparations towards initiation of the U.S. pivotal study of C-Scan during 2021. In November 2020, we achieved a major milestone, including finalizing of our proposed pivotal design and submission of our investigational device exemption (IDE) to the U.S. Food and Drug Administration (FDA) and we are in the process of responding to comments that we received from the FDA. We plan to provide an update on the next steps and a more specific timeline as we advance further in the IDE review process.

Our primary objective continues to be gaining approval of C-Scan in the U.S. We continue to optimize C-Scan's functionality and patient experience in preparation for the upcoming U.S. pivotal study through additional clinical data collection at Israel sites. To this end, we have finalized a clinical trial protocol for a study in Israel and identified over 10 clinical trial sites to enroll up to 250 average risk patients. In ongoing studies in Israel enrollment pace has been slower than expected due to manufacturing delays and the COVID-19 pandemic. Nevertheless, our team is committed to accelerating patient recruitment during 2021.

Manufacturing: The Check-Cap team has diligently worked with its suppliers to ensure device manufacturing, and supply chain and quality infrastructure to facilitate our planned pivotal study. While we have experienced typical delays expected during a manufacturing line expansion, recovery plans are underway. We are happy to report that earlier in the month, the Israel Innovation Authority approved a grant of up to $750,000 to support an R&D to manufacturing transition along with co-investment by Check Cap of the same amount. These funds are planned to also cover an in-house X-Ray source manufacturing line. We are also pleased to announce that to support our US pivotal study, we have signed a distribution agreement with GE Healthcare.

NASDAQ Listing Compliance: On January 26, 2021, we were notified by Nasdaq that we regained compliance with the minimum $1.00 bid price rule.

Cash balance: To support our activities, in 2020 we raised gross proceeds of $16.3 million in a private placement and registered direct offerings as well as $9.6 million in a warrant exercise financing of ordinary shares and warrants. During January 2021, following the increase of our share price in the market, certain existing warrant holders exercised their warrants at exercise prices ranging from $0.75-$0.80, which generated total gross proceeds of approximately $18.0 million to the Company. This cash strengthens our financial position. As of the date of this letter, we estimate that we have approximately $34.8 million of cash and cash equivalents. We continue to use the proceeds from each of these transactions and the recent exercise of warrants for general corporate purposes, mostly towards preparations for our U.S. pivotal study in 2021.

Patents: We remain highly active in protecting our intellectual property with an accumulation of 46 granted patents and 2 allowed patents in main world markets, covering various aspects of our technology, as well as 19 additional pending patents in the pipeline. In 2020, we were granted three new patents in the U.S. and Europe, which include (i) a new image reconstruction algorithm methodology activated by data received from our X-ray based imaging capsule. This patent is expected to give us broad protection with respect to our novel X-ray based imaging capsule and the image reconstruction algorithms developed for C-Scan, (ii) an innovative body-worn

antenna used by our capsule's tracking system which enables optimal communication with the capsule inside the patient and, (iii) a patent for a unique drug delivery capsule, which is part of our forward-looking strategy.

The technology patented in this new drug delivery application allows for precise localization of the capsule within the patient and programmable site-specific drug delivery. It offers complete control over the amount of drug dispensed at any location along the gastrointestinal tract, which could potentially improve the drug's efficacy whi reducing unwanted systemic side effects. This may represent a new product for Check-Cap in the future as this new delivery mechanism is likely to extend the drug patent life, which could potentially make it an attractive option for a collaboration with a pharmaceutical partner.

COVID-19: During 2020 and to date, Check Cap, like most other companies, faced operational disruptions relate to the COVID-19 pandemic, resulting in delays to manufacturing and patient enrollment. We implemented and continue to implement health and safety measures according to the Israel Ministry of Health's guidelines around COVID-19. Despite these limitations and the recent quarantines, Check-Cap has still advanced C-Scan and preparations for substantial expansion of the clinical data collection on average risk patients at leading Israeli site

Looking Forward at 2021: To conclude, we believe we have made significant progress on a number of fronts ir this extremely challenging past year. The U.S. market remains our primary objective in 2021 and onward. We are focused on obtaining IDE approval, completing the pivotal study, and achieving clearance and launch of our disruptive C-Scan device in this important market. In parallel, we aim to assess opportunities to launch C-Scan in other international markets, primarily where we have been granted regulatory approval.

We believe C-Scan has the potential to significantly contribute to improving the current colorectal cancer screeni landscape worldwide through cancer prevention, ultimately, enabling millions of people to avoid the disruption ar morbidity associated with cancer treatment and its progression. Currently, colonoscopy is the gold standard for th detection of colorectal polyps, but about one in three adults[1] among the targeted screening population avoids having a colonoscopy in the U.S., and adherence in other regions of the world, such as Europe and Asia, is even lower[2,3]. Most patient-friendly CRC screening tests currently available, or poised to enter the market, such as feca or liquid biopsy tests, are primarily designed to detect cancer and demonstrate low sensitivity in detecting pre-cancerous polyps. As such, they do not necessarily provide patients with the time window to pre-empt the disease We believe there is a genuine unmet need for a patient-friendly screening option, such as C-Scan, that can overcome barriers to colonoscopy screening while also enabling pre-cancerous polyp detection.

We would like to take the opportunity to thank our employees who work tirelessly in support of our mission and th advancement of C-Scan, and you, our shareholders, for your continued partnership. Your continued support is tremendously appreciated, and we would like to maintain our open dialogue going forward.

We look forward to providing updates on our progress in the near future.

Sincerely,

Alex Ovadia

Chief Executive Officer

Check-Cap

About Check-Cap

Check-Cap is a clinical stage medical diagnostics company aiming to redefine colorectal cancer (CRC) screening and prevention through the introduction of C-Scan, the first and only patient-friendly preparation-free screening test to detect polyps before they may transform into colorectal cancer. The Company's disruptive capsule-based screening technology aims to significantly increase screening adherence worldwide and help millions of people to stay healthy through preventive CRC screening. C-Scan uses an ultra-low dose X-ray capsule, an integrated positioning, control and recording system, as well as proprietary software to generate a 3D map of the inner lining of the colon. C-Scan is non-invasive and requires no preparation or sedation, allowing the patients to continue their daily routine with no interruption as the capsule is propelled through the gastrointestinal tract by natural motility.

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 "Forward-looking Statements" and "Risk Factors" in the Company's Annual Report on Form 20-F for the year ended December 31, 2019 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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