



# Check-Cap Reports First Quarter 2021 Financial Results and Corporate Update

ISFIYA, Israel, May 12, 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 (CRC), today announced financial results for the first quarter ended March 31, 2021 and provided a corporate update.

## Q1 2021 and Recent Highlights:

- The U.S. Food and Drug Administration (FDA) has approved the Company's Investigational Device Exemption (IDE) application permitting Check-Cap to begin a pivotal study of C-Scan in the U.S.
- The FDA has granted the Company Breakthrough Device Designation for C-Scan.
- The Company continues to scale up manufacturing to support upcoming clinical trials, primarily the Company's U.S. pivotal study.
- Due to technical issues associated with a single source supplier, the Company has recently experienced some manufacturing delays, but continues to expand its entire production process to meet its target manufacturing capacity. The Company expects a delay in its clinical trials, including the initiation of the U.S. pivotal trial, which is now projected to begin by the end of the first quarter of 2022.
- Strengthened balance sheet during the first quarter of 2021 through a total of \$19.2 million proceeds from warrant exercises. Cash and cash equivalents, restricted cash and short-term bank deposits as of March 31, 2021 were \$34.0 million.

"We met a crucial milestone this quarter with the FDA approval of the IDE to begin the pivotal trial of C-Scan in the U.S.," said Alex Ovadia, chief executive officer of Check-Cap. "While we anticipate a slight delay in our clinical trials, including the U.S. pivotal trial initiation, now projected for March 2022, we are laser-focused on advancing manufacturing activities to ensure a successful trial launch. We look forward to continuing to advance C-Scan as a colorectal cancer screening patient-friendly solution that has potential to enable early intervention and cancer prevention."

## Financial Results for the First Quarter Ended March 31, 2021

Research and development expenses were \$2.4 million for the three months ended March 31, 2021, compared to \$2.5 million for the same period in 2020. The decrease is primarily due to a \$0.3 million grant received from the Israel Innovation Authority, which amount is reduced from research and development expenses, and \$0.2 million decrease in other expenses and clinical-related expenses, offset in part by a \$0.2 million increase in material and subcontractors' expenses and \$0.2 million increase in salary and related expense.

General and administrative expenses were \$1.2 million for the three months ended March 31, 2021, compared to \$1.0 million for the same period in 2020. The increase is primarily due to a \$0.2 million increase in professional services and other expenses.

Operating loss was \$3.6 million for the three months ended March 31, 2021, compared to \$3.4 million for the same period in 2020.

Finance expense was \$9,000 for the three months ended March 31, 2021, compared to \$12,000 for the same period in 2020.

Net loss was \$3.6 million for the three months ended March 31, 2021, compared to \$3.4 million for the same period 2020.

Cash and cash equivalents, restricted cash and short-term bank deposits as of March 31, 2021 were \$34.0 million as compared to \$18.1 million as of December 31, 2020. During the first quarter of 2021, certain warrant holders exercised warrants to purchase an aggregate 24,204,682 ordinary shares, which had been issued in 2020, at exercise prices ranging from \$0.75-\$0.80, which generated total gross proceeds of approximately \$19.2 million to the Company.

The number of outstanding ordinary shares as of March 31, 2021 was 70,468,260. As of May 10, 2021, the number of our outstanding ordinary shares was 70,472,316.

## About Check-Cap

Check-Cap is a clinical stage medical diagnostics company aiming to redefine colorectal cancer (CRC) screening

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 to enable early intervention and cancer prevention. 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 as it travels naturally along the gastrointestinal tract. C-Scan is non-invasive and requires no sedation. Unlike other capsule technologies, it requires no bowel preparation, allowing the patients to continue their daily routine with no interruption. C-Scan is not intended to replace colonoscopy. A positive C-Scan result should be followed by colonoscopy.

## 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, 2020 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.

## Investor Contacts

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## **CHECK CAP LTD.** **CONSOLIDATED UNAUDITED BALANCE SHEETS** (U.S. dollars in thousands except share and per share data)

	<b>March 31, 2 0 2 1</b>	<b>December 31, 2 0 2 0</b>
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	15,194	7,703
Restricted cash	350	350
Short-term bank deposit	18,470	10,079
Prepaid expenses and other current assets	440	285
<b>Total current assets</b>	<b>34,454</b>	<b>18,417</b>
<b>Non-current assets</b>		
Property and equipment, net	847	823
Operating lease	1,223	398
<b>Total non-current assets</b>	<b>2,070</b>	<b>1,221</b>
<b>Total assets</b>	<b>36,524</b>	<b>19,638</b>
<b>Liabilities and shareholders' equity</b>		
<b>Current liabilities</b>		
Accounts payable and accruals		
Trade	1,028	862
Other	295	345
Employees and payroll accruals	1,718	1,510

Operating lease liabilities	327	264
<b>Total current liabilities</b>	<b>3,368</b>	<b>2,981</b>
<b>Non-current liabilities</b>		
Royalties provision	196	154
Operating lease liabilities	856	125
<b>Total non-current liabilities</b>	<b>1,052</b>	<b>279</b>
<b>Shareholders' equity</b>		
Share capital, Ordinary shares, 2.4 NIS par value (360,000,000 authorized shares as of March 31, 2021 and December 31, 2020; 70,468,260 and 46,239,183 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively)	49,763	31,646
Additional paid-in capital	76,890	75,715
Accumulated deficit	(94,549)	(90,983)
<b>Total shareholders' equity</b>	<b>32,104</b>	<b>6,234</b>
<b>Total liabilities and shareholders' equity</b>	<b>36,524</b>	<b>19,638</b>

**CHECK CAP LTD.**  
**CONSOLIDATED UNAUDITED STATEMENTS OF OPERATIONS**  
(U.S. dollars in thousands, except share and per share data)

	Three months ended March 31,	
	2021	2020
Research and development expenses, net	2,406	2,462
General and administrative expenses	1,151	957
<b>Operating loss</b>	<b>3,557</b>	<b>3,419</b>
Finance loss, net	9	12
Loss before income tax	3,566	3,431
<b>Net loss for the period</b>	<b>3,566</b>	<b>3,431</b>
<b>Comprehensive loss</b>	<b>3,566</b>	<b>3,431</b>
<b>Loss per share:</b>		
Net loss per ordinary share basic and diluted	0.05	0.34
Weighted average number of ordinary shares outstanding - basic and diluted	68,071,059	9,971,098

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**CONSOLIDATED UNAUDITED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY**  
(U.S. dollars in thousands, except share and per share data)

	Number of ordinary shares	Amount	Additional paid-in capital	Accumulated deficit	Total shareholders equity
<b>Balance as of January 1, 2021</b>	<b>46,239,183</b>	<b>\$ 31,646</b>	<b>\$ 75,715</b>	<b>\$ (90,983)</b>	<b>\$ 16,378</b>
Exercise of warrants, net of issuance expenses in an amount of \$22 RSU's	24,204,682	18,099	1,120	-	19,219
vesting Share-based compensation	24,395	18	(18)	-	-

<b>Net loss</b>	-	-	73	-	73
<b>Balance as of March 31, 2021</b>	<b>70,468,260</b>	<b>\$ 49,763</b>	<b>\$ 76,890</b>	<b>\$ (94,549)</b>	<b>\$ 32,104</b>

	<b>Number of ordinary shares</b>	<b>Amount</b>	<b>Additional paid-in capital</b>	<b>Accumulated deficit</b>	<b>Total shareholders equity</b>
<b>Balance as of January 1, 2020</b>	<b>8,272,908</b>	<b>\$ 5,407</b>	<b>\$ 77,964</b>	<b>\$ (77,137)</b>	<b>\$ 6,234</b>
Issuance of ordinary shares in private placement, net of issuance expenses in an amount of \$30	2,720,178	1,894	2,837	-	4,731
RSU's vesting	6,633	4	(4)	-	-
Share-based compensation	-	-	123	-	123
<b>Net loss</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>(3,431)</b>	<b>(3,431)</b>
<b>Balance as of March 31, 2020</b>	<b>10,999,719</b>	<b>\$ 7,305</b>	<b>\$ 80,920</b>	<b>\$ (80,568)</b>	<b>\$ 7,657</b>


**CHECK-CAP LTD.**  
**CONSOLIDATED UNAUDITED STATEMENTS OF CASH FLOWS**  
**(U.S. dollars in thousands, except share and per share data)**

	<b>Three months ended March 31,</b>	
	<b>2021</b>	<b>2020</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	(3,566)	(3,431)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	43	34
Share-based compensation	73	123
Financial income, net	(57)	(15)
<b>Changes in assets and liabilities items:</b>		
Decrease (increase) in prepaid and other current assets and non-current assets	(142)	101
Increase (decrease) in trade accounts payable, accruals and other current liabilities	85	(325)
Increase in employees and payroll accruals	208	78
Increase in royalties provision	42	-
<b>Net cash used in operating activities</b>	<b>(3,314)</b>	<b>(3,433)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchase of property and equipment	(33)	(57)
Investment in short-term bank and other deposits	(8,381)	(2,258)
<b>Net cash provided by (used in) investing activities</b>	<b>(8,414)</b>	<b>(2,315)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Exercise of warrants into ordinary shares, net of issuance expenses	19,219	-
Issuance of ordinary shares in private placement, net of issuance expenses	-	4,731
<b>Net cash provided by financing activities</b>	<b>19,219</b>	<b>4,731</b>
<b>Net increase (decrease) in cash, cash equivalents and restricted cash</b>	<b>7,491</b>	<b>(1,017)</b>
<b>Cash, cash equivalents and restricted cash at the beginning of the period</b>	<b>8,053</b>	<b>8,039</b>
<b>Cash, cash equivalents and restricted cash at the end of the period</b>	<b>15,544</b>	<b>7,018</b>
<b>Supplemental disclosure of non-cash flow information:</b>		
Purchase of property and equipment included in accounts payable and accrued expenses	32	59
Assets acquired under operating leases	916	-

## Supplemental disclosure of cash flow information

SOURCE Check-Cap Ltd.

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Additional assets available online:  [Photos](#) <sup>(1)</sup>

<https://ir.check-cap.com/2021-05-12-Check-Cap-Reports-First-Quarter-2021-Financial-Results-and-Corporate-Update>