



Check-Cap Reports Fourth Quarter and Full Year 2019 Financial Results

**Company planning to initiate a U.S. pivotal study of the C-Scan System in late 2020
Strengthened balance sheet through a \$4.76 million private placement of ordinary shares**

ISFIYA, Israel, March 6, 2020 /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 transform into colorectal cancer, today announced financial results for the fourth quarter and full year ended December 31, 2019.

2019 and Recent Highlights:

- Continued to advance the pre-submission process with FDA towards the initiation of a pivotal trial of the C-Scan System in late 2020
- In February 2020, strengthened its balance sheet through a \$4.76 million private placement of ordinary share
- In December 2019, announced positive results from the U.S. pilot study of C-Scan that was performed at the NYU Grossman School of Medicine and Mayo Clinic of Rochester
- In August 2019, announced the completion of manufacturing line transfer implementation and qualification for the C-Scan System to our manufacturing partner, GE Healthcare, a leading global medical technology and life sciences company
- In July 2019, announced positive results from the post-CE approval study of C-Scan, which further validated the importance and potential of the system.

"We ended 2019 on a high note with the successful completion of our U.S. pilot study of the C-Scan System which, pending FDA approval, sets the stage for the initiation of a U.S. pivotal trial in late 2020," said Alex Ovadia, Chief Executive Officer of Check-Cap. "There exists a significant global unmet need for a colon cancer screening and detection technology that is preparation free and non-invasive compared to the current standard of care, colonoscopy. We believe the patient-friendly C-Scan System can increase screening rates globally by eliminating the rigorous and unpleasant preparation that colonoscopy and other tests require.

"Colon cancer is a highly preventable disease, and an increase in global screening rates that we believe C-Scan can facilitate will result in earlier detection and improved long-term patient outcomes. We look forward to initiating a U.S. pivotal trial, as we work to introduce this groundbreaking technology in the important US market," Mr. Ovadia concluded.

Financial Results for the Fourth Quarter Ended December 31, 2019

Research and development expenses, net, were \$2.8 million for the three months ended December 31, 2019, compared to \$2.4 million for the same period in 2018. The increase is primarily due to a \$0.4 million increase in salaries and related expenses and a \$0.2 million increase in materials, subcontractor and consultant expenses, primarily in connection with our U.S. pilot study and regulatory expenses, offset in part by a \$0.1 million decrease in share-based compensation expenses.

General and administrative expenses were \$1.0 million for the three months ended December 31, 2019, compared to \$1.1 million for the same period in 2018. The decrease is primarily due to a \$0.2 million decrease in professional services, offset in part by a \$0.1 million increase in salaries and related expenses.

Operating loss was \$3.9 million for the three months ended December 31, 2019, compared to an operating loss of \$3.5 million for the same period in 2018.

Financial income, net was \$19,000 for the three months ended December 31, 2019, compared to \$366,000 for the same period in 2018. The change is primarily as a result of a change in royalties' provision of \$3,000 in 2019 compared to \$295,000 in 2018 and \$29,000 financial income from interest compared to \$80,000 in 2018.

Net loss was \$3.8 million for the three months ended December 31, 2019, compared to \$3.1 million for the same period in 2018.

Cash and cash equivalents, restricted cash and short-term bank deposits as of December 31, 2019 were \$8.0 million as compared to \$14.6 million as of December 31, 2018. Subsequent to the end of the fourth quarter, in February

2020, we raised gross proceeds of \$4.76 million in a private placement.

Financial Results for the Twelve Months Ended December 31, 2019

Research and development expenses, net, were \$10.5 million for the twelve months ended December 31, 2019, compared to \$7.6 million for the same period in 2018. The increase is primarily due to a \$0.9 million increase in salaries and related expenses, \$0.2 million increase in share-based compensation, \$0.4 million increase in materials, \$0.5 million increase in subcontractor and consultant expenses and a \$0.8 million increase in other research and development expenses, mainly related to our clinical trials, primarily in connection with our post-CE Mark clinical study and the U.S. pilot study. The increase in research and development expenses, net between 2019 and 2018 also includes a \$0.1 million decrease in grants received from the Israel Innovation Authority.

General and administrative expenses were \$3.6 million for the twelve months ended December 31, 2019, compared to \$3.5 million for the same period in 2018. The increase is primarily due to an increase of \$0.4 million in share-based compensation expenses and \$0.2 million increase in other general expenses, offset in part by a \$0.3 million decrease in salaries and related expenses and \$0.1 million decrease in professional services expenses.

Operating loss was \$14.1 million for the twelve months ended December 31, 2019, compared to \$11.1 million in the same period in 2018.

Finance income, net, was \$234,000 for the twelve months ended December 31, 2019, compared to \$473,000 for the same period in 2018. The decrease in finance income, net was primarily as a result of a \$252,000 decrease in finance income from a change in royalties' provision.

Net loss was \$13.8 million for the twelve months ended December 31, 2019, compared to \$10.6 million for the same period in 2018.

Net cash used in operating activities was \$12.8 million for the twelve months ended December 31, 2019, compared to \$10.1 million for the same period in 2018.

The number of outstanding ordinary shares as of December 31, 2019 was 8,272,906. Subsequent to December 31, 2019, the Company issued 2,720,178 ordinary shares in a private placement. As of February 25, 2020, the number of our outstanding ordinary shares was 10,997,714.

A copy of the Company's annual report on Form 20-F for the year ended December 31, 2019 has been filed with the U.S. Securities and Exchange Commission at www.sec.gov and posted on the Company's investor relations website at <http://ir.check-cap.com/home>. The Company will deliver a hard copy of its annual report, including its complete audited consolidated financial statements, free of charge, to its shareholders upon request to Mira Rosenzweig, Chief Financial Officer, at mira.rosenzweig@check-cap.com.

[Financial Tables to Follow]

About Check-Cap

Check-Cap is a clinical stage medical diagnostics company aiming to redefine colorectal cancer (CRC) prevention through the introduction of C-Scan®, the first and only patient-friendly preparation-free screening test to detect polyps before they transform into colorectal cancer. The Company's disruptive capsule-based screening technology aims to significantly increase screening adherence worldwide and enable millions of people to stay healthy. The C-Scan System 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.

CHECK CAP LTD.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands except share data)

	December 31,	
	2019	2018
Assets		
Current assets		
Cash and cash equivalents	7,685	8,572
Restricted cash	350	350
Short-term bank deposit	-	5,643
Prepaid expenses and other current assets	400	419
Total current assets	8,435	14,984
Non-current assets		
Property and equipment, net	540	452
Operating lease assets	454	-
Total non-current assets	994	452
Total assets	9,429	15,436
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable and accruals		
Trade	989	1,113
Other	490	214
Other current liabilities	-	35
Employees and payroll accruals	1,101	859
Operating lease liabilities- current	222	-
Total current liabilities	2,802	2,221
Non-current liabilities		
Royalties provision	182	185
Operating lease liabilities- net of current portion	211	-
Total non-current liabilities	393	185
Shareholders' equity		
Share capital, Ordinary shares, 2.4 NIS par value (90,000,000 and 30,000,000 authorized shares as of December 31, 2019 and 2018, respectively; 8,272,908 and 5,330,684 shares issued and outstanding as of December 31, 2019 and 2018, respectively)	5,407	3,456
Additional paid-in capital	77,964	72,888
Accumulated other comprehensive loss	-	(13)
Accumulated deficit	(77,137)	(63,301)
Total shareholders' equity	6,234	13,030
Total liabilities and shareholders' equity	9,429	15,436

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

Year

Three months

	<u>ended</u> <u>December 31,</u>		<u>ended</u> <u>December 31,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Research and development expenses, net	10,474	7,618	2,819	2,396
General and administrative expenses	3,595	3,445	1,028	1,073
Operating loss	<u>14,069</u>	<u>11,063</u>	<u>3,847</u>	<u>3,469</u>
Finance income, net	233	473	19	365
Loss before income tax	13,836	10,590	3,828	3,104
Taxes on income	-	(1)	-	-
Net loss for the period	<u>13,836</u>	<u>10,589</u>	<u>3,828</u>	<u>3,104</u>
Comprehensive loss:				
Net loss	13,836	10,589	3,828	3,104
Change in fair value of cash flow hedge	(13)	13	-	(28)
Comprehensive loss	<u>13,823</u>	<u>10,602</u>	<u>3,828</u>	<u>3,076</u>
Loss per share:				
Net loss per ordinary share basic and diluted	1.73	2.61	0.46	0.58
Weighted average number of ordinary shares outstanding - basic and diluted (in thousands)	<u>7,986</u>	<u>4,058</u>	<u>8,270</u>	<u>5,352</u>

CHECK-CAP LTD.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. dollars in thousands)

	<u>Year</u> <u>ended</u> <u>December 31,</u>		<u>Three months</u> <u>ended</u> <u>December 31,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
CASH FLOWS FROM OPERATING ACTIVITIES				
Net loss	(13,836)	(10,589)	(3,829)	(3,104)
Adjustments required to reconcile net loss to net cash used in operating activities:				
Depreciation	115	147	31	29
Share-based compensation	516	(65)	110	206
Financial expenses (income), net	40	(13)	85	110
Changes in assets and liabilities items:				
Decrease (increase) in prepaid and other current assets and non-current assets	(420)	(13)	(383)	77
Increase (decrease) in trade accounts payable, accruals and other current liabilities	503	416	399	356
Increase (decrease) in employees and payroll accruals	242	258	266	(92)
Decrease in royalties provision	(3)	(255)	(10)	(294)
Net cash used in operating activities	<u>(12,843)</u>	<u>(10,114)</u>	<u>(3,331)</u>	<u>(2,712)</u>
CASH FLOWS FROM INVESTING ACTIVITIES				
Purchase of property and equipment	(167)	(94)	(36)	(80)
Proceeds from (investment in) short-term bank and other deposit	5,612	(5,629)	3,939	3,371
Net cash provided by (used in) investing activities	<u>5,445</u>	<u>(5,723)</u>	<u>3,903</u>	<u>3,291</u>
CASH FLOWS FROM FINANCING ACTIVITIES				

Exercise of warrants into ordinary shares	-	-	-	(4)
Issuance of ordinary shares in the registered direct offerings, net of issuance expenses	6,511	(30)	-	(30)
Issuance of ordinary shares in the 2018 Public Offering	-	17,792	-	(66)
Net cash provided by financing activities	6,511	17,762	-	(100)
Net increase (decrease) in cash, cash equivalents and restricted cash	(887)	1,925	572	437
Cash, cash equivalents and restricted cash at the beginning of the period	8,922	6,997	7,463	8,485
Cash, cash equivalents and restricted cash at the end of the period	8,035	8,922	8,035	8,922
Supplemental disclosure of non-cash flow information:				
Cashless exercise of warrants to purchase ordinary shares into ordinary shares	24	33	11	24
Purchase of property and equipment	32	3	32	35
Recognition of operating leases and operating lease liabilities from adoption of ASU 2016-02	369	-	-	-
Right of use asset obtained in exchange for new operating lease	223	-	117	-
Supplemental disclosure of cash flow information				
Cash paid for taxes	15	5	-	-

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<https://ir.check-cap.com/2020-03-06-Check-Cap-Reports-Fourth-Quarter-and-Full-Year-2019-Financial-Results>