



Check-Cap Reports Third Quarter 2019 Financial Results and Corporate Highlights

Successfully launched U.S. pilot study and reported positive final results from post-CE approval study of the C-Scan System

ISFIYA, Israel, Nov. 6, 2019 /PRNewswire/ -- [Check-Cap Ltd.](#) (the "Company" or "Check-Cap") (NASDAQ: CHEK) (NASDAQ: CHEKW), (NASDAQ: CHEKZ), a clinical stage medical diagnostics company advancing the development of the C-Scan® System, the first and only preparation-free ingestible scanning capsule based system for the prevention of colorectal cancer through the detection of precancerous polyps, today announced financial results for the third quarter and nine months ended September 30, 2019.

Third Quarter and Recent Highlights:

- Continued to advance the U.S. pilot study of the C-Scan System, conducted at the NYU School of Medicine and Mayo Clinic, toward completion by year-end 2019.
- Announced positive final results from its post-CE approval study of the C-Scan System. The study met its primary endpoint, achieving sensitivity of 76% in patients with polyps ≥ 10 mm and specificity of 82% in all patients, compared to fecal immunochemical test (FIT) that achieved 29% sensitivity and 96% specificity. In addition, the C-Scan System detected all 4 patients (100%) with polyps ≥ 40 mm, while FIT detected only 1 of the 4 patients (25%) with polyps ≥ 40 mm. Overall, the C-Scan System achieved a sensitivity of 66% in all patients (including patients with polyps < 10 mm), while FIT achieved a sensitivity of 23% for the same population.
- Announced completion of the manufacturing line transfer implementation and qualification for the C-Scan System operated by GE Healthcare.
- Strengthened leadership team with appointment of Dr. Vardit Segal as Vice President of Clinical Affairs.

"During the third quarter of 2019, we continued to advance our U.S. pilot study of the C-Scan System and anticipate study completion by year-end," said Alex Ovadia, Chief Executive Officer of Check-Cap. "If the results of the pilot study are positive, we intend to meet with the FDA as expeditiously as possible to obtain approval to initiate a pivotal trial next year. At the same time, we continue to collect additional clinical data, as we work to introduce this novel screening and detection technology to the broadest possible patient population.

"Colorectal cancer screening rates remain low globally, generally believed to be due in large part to the burdensome preparation required by currently available tests. As a result, colorectal cancer is the third most diagnosed cancer, despite the lengthy opportunity for prevention or early detection that exists given that can take up to ten years for a precancerous polyp to become cancerous. We believe a preparation-free ingestible capsule based system such as the C-Scan System can meaningfully increase screening rates, resulting in superior long-term outcomes for patients and significant savings for healthcare systems," concluded M Ovadia.

Financial Results for the Third Quarter Ended September 30, 2019

Research and development expenses, net, were \$2.7 million for the three months ended September 30, 2019, compared to \$1.9 million for the same period in 2018. The increase is primarily due to an increase of \$0.6 million in expenses for the ongoing pilot study and subcontractors and materials, as well an increase of \$0.1 million in salaries and related expenses as a result of expansion in head count and \$0.2 million decrease in grants received in 2018 from the Israel Innovation Authority (IIA), which was recorded as a credit to research and development expenses in 2018.

General and administrative expenses were \$0.8 million for the three months ended September 30, 2019, compared to \$0.9 million for the same period in 2018.

Operating loss was \$3.6 million for the three months ended September 30, 2019, compared to an operating loss of \$2.8 million for the same period in 2018.

Financial income, net was \$62,000 for the three months ended September 30, 2019, compared to \$99,000 for the same period in 2018.

Net loss was \$3.5 million for the three months ended September 30, 2019, compared to \$2.7 million for the same period in 2018.

Cash and cash equivalents, restricted cash and short-term bank deposits totaled \$11.5 million as of September 30, 2019, compared with \$14.7 million at June 30, 2019 and \$14.6 million as of December 31, 2018.

Financial Results for the Nine Months Ended September 30, 2019

Research and development expenses, net were \$7.7 million for the nine months ended September 30, 2019, compared to \$5.2 million for the same period in 2018. The increase is primarily due to an increase of \$1.6 million in expenses related to the post-CE approval study and ongoing pilot study and subcontractors and materials, as well as an increase of \$0.5 million in salaries and related expenses as a result of expansion in head count, an increase of \$0.2 million in share-based compensation and a \$0.1 million decrease in grants received from the IIA.

General and administrative expenses were \$2.6 million for the nine months ended September 30, 2019, compared to \$2.4 million for the same period in 2018. The increase was primarily due to an increase of \$0.4 million in share-based compensation and \$0.1 million in professional services. This increase was partially offset by a \$0.4 million decrease in salaries and related expenses.

Operating loss was \$10.2 million for the nine months ended September 30, 2019, compared to \$7.6 million in the same period in 2018.

Finance income, net was \$215,000 for the nine months ended September 30, 2019, compared to \$108,000 for the same period in 2018. The increase was due to income from interest on bank deposits.

Net loss was \$10.0 million for the nine months ended September 30, 2019, compared to \$7.5 million for the same period in 2018.

Net cash used in operating activities was \$9.5 million for the nine months ended September 30, 2019, compared to \$7.3 million for the same period in 2018.

The number of outstanding ordinary shares as of September 30, 2019 was 8,266,062. This number includes the 2,906,376 ordinary shares that were issued in the February 2019 registered direct offering.

[Financial Tables to Follow]

About Check-Cap

Check-Cap is advancing the development of the C-Scan® System, the first and only preparation-free ingestible scanning capsule based system for the prevention of colorectal cancer (CRC) through the detection of precancerous polyps. The patient-friendly test has the potential to increase screening adherence and reduce the overall incidence of CRC. The C-Scan System utilizes 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 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, 2018 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 UNAUDITED BALANCE SHEETS
(U.S. dollars in thousands)

	<u>September 30, 2019</u>	<u>December 31, 2018</u>
Assets		
Current assets		
Cash and cash equivalents	7,113	8,572
Restricted cash	350	350
Short-term bank deposit	4,015	5,643
Prepaid expenses and other current assets	437	419
Total current assets	<u>11,915</u>	<u>14,984</u>
Non-current assets		
Property and equipment, net	500	452
Operating leases	481	-
Total non-current assets	<u>981</u>	<u>452</u>
Total assets	<u>12,896</u>	<u>15,436</u>
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable and accruals		
Trade	969	1,113
Other	484	249
Employees and payroll accruals	835	859
Operating lease liabilities	197	-
Total current liabilities	<u>2,485</u>	<u>2,221</u>

Non-current liabilities		
Royalties provision	192	185
Operating lease liabilities	266	-
Total non-current liabilities	<u>458</u>	<u>185</u>
Shareholders' equity		
Share capital	5,402	3,456
Additional paid-in capital	77,859	72,888
Accumulated other comprehensive loss	-	(13)
Accumulated deficit	(73,308)	(63,301)
Total shareholders' equity	<u>9,953</u>	<u>13,030</u>
Total liabilities and shareholders' equity	<u>12,896</u>	<u>15,436</u>

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

	Nine months ended September 30,		Three months ended September 30,	
	2019	2018	2019	2018
Research and development expenses, net	7,655	5,222	2,746	1,865
General and administrative expenses	2,567	2,372	818	937
Operating loss	<u>10,222</u>	<u>7,594</u>	<u>3,564</u>	<u>2,802</u>
Finance income, net	215	108	62	99
Loss before income tax	<u>10,007</u>	<u>7,486</u>	<u>3,502</u>	<u>2,703</u>
Taxes on income	-	(1)	-	-
Net loss	<u>10,007</u>	<u>7,485</u>	<u>3,502</u>	<u>2,703</u>
Other comprehensive loss:				
Change in fair value of cash flow hedge	13	-	-	-
Comprehensive loss	<u>10,020</u>	<u>7,485</u>	<u>3,502</u>	<u>2,703</u>
Net loss per ordinary share - basic and diluted	<u>1.27</u>	<u>2.07</u>	<u>0.42</u>	<u>0.5</u>
Weighted average number of ordinary shares outstanding - basic and diluted	<u>7,863</u>	<u>3,622</u>	<u>8,254</u>	<u>5,356</u>

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

	Nine months ended September 30,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss for the period	(10,007)	(7,485)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	84	118
Share-based compensation	406	(271)
Financial (income) expenses, net	(45)	(81)
Increase in royalties provision	7	40
Changes in assets and liabilities items:		
Increase in prepaid and other current assets and non-current assets	(37)	(90)
Increase in trade accounts payable, accruals and other current liabilities	104	60
Increase (decrease) in employees and payroll accruals	(24)	349
Net cash used in operating activities	(9,512)	(7,360)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(131)	(14)

Proceeds from short-term bank deposits, net	1,573	(9,014)
Net cash provided by (used in) investing activities	1,573	(9,014)
CASH FLOWS FROM FINANCING ACTIVITIES		
Issuance of ordinary shares in the 2018 public offering, net of issuance expenses	-	17,862
Issuance of ordinary shares in the 2019 registered direct offering, net of issuance expenses	6,511	-
Net cash provided by financing activities	6,511	17,862
Net increase (decrease) in cash and cash equivalents and restricted cash	(1,459)	1,488
Cash and cash equivalents and restricted cash at the beginning of the period	8,922	6,997
Cash and cash equivalents and restricted cash at the end of the period	7,463	8,485

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

Supplemental information for Cash Flow:

	Nine months ended September 30,	
	2019	2018
<u>Supplemental disclosure of non-cash information</u>		
Cashless exercise of warrants to purchase ordinary shares into ordinary shares	19	37
Purchase of property and equipment on credit	-	40
Recognition of operating leases and operating lease liabilities from adoption of ASU 2016-02	490	-
Assets acquired under operating leases	106	

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