Check-Cap Reports Third Quarter 2017 Financial Results

ISFIYA, Israel and BOSTON, Nov. 6, 2017 /PRNewswire/ -- Check-Cap Ltd. (the "Company" or "Check-Cap") (NASDAQ: CHEK; CHEKW), a clinical-stage medical diagnostics company engaged in the development of C-Scan®, an ingestible capsule for preparation-free, colorectal cancer screening, today announced its financial results for the third quarter and nine months ended September 30, 2017.

Recent Highlights

Continued advancements on C-Scan regulatory, clinical performance, and development programs:

- Filed CE Mark registration for the C-Scan system. Data from the multi-center clinical safety and performance study to support the submission showed safety and encouraging results for detecting patients with polyps in an un-prepped colon. Data from the study demonstrated a 44% sensitivity for patients with polyps in the 45 subjects included in the analysis. Specificity was 89%. Sensitivity strongly correlated (R-squared = 0.98) to the percentage of the colon scanned. Sensitivity was 78% and 100% for subjects where greater than 50% and 70% of the colon was scanned, respectively.
- Late breaking, oral presentation of clinical safety and performance study abstract, "Clinical Performance of a Novel X-ray Based Imaging Capsule for Colonic Screening", at the United European Gastroenterology (UEG) Week 2017 in Barcelona, Spain on October 30th.
- Progress made with advanced C-Scan version. Subsequent improvements made to software algorithms showed enhanced colon scanning in an internal analysis using the original 45 subjects from the multi-center study. The number of subjects with greater than 50% of the colon scanned increased by 74% to 33/45 from 19/45. Further algorithm optimization and clinical evaluations are ongoing.

Bill Densel, CEO of Check-Cap, stated: "We are pleased to have filed our CE Mark application during the quarter, with encouraging clinical data supporting this submission, which was presented at the late breaking session at UEG." Mr. Densel continued, "We are committed to providing an alternative to today's invasive and preparation-intensive approaches to colorectal cancer prevention. We continue to make progress with our short-term development objectives for an advanced C-Scan version, which we believe will enhance performance for consistent scan coverage. We also look forward to EU post-market and US pilot trial initiations, expected to begin in the first half of 2018."

Financial Results for the Third Quarter Ended September 30, 2017

Research and development expenses, net were $1.6 million in the three months ended September 30, 2017, compared to $1.0 million in the same period in 2016. The increase is primarily attributable to (1) $332,000 decrease in grant received from the Israel Innovation Authority (the "IIA") which was credited to research and development expenses, net; (2) $62,000 increase in share based compensation; and (3) $182,000 related primarily to the Company's clinical trial to support CE Marking of the C-Scan system.

General and administrative expenses were $0.8 million in the three months ended September 30, 2017, in line with expenses for the same period in 2016.

Operating loss was $2.4 million for the three months ended September 30, 2017, compared to $1.8 million in the same period in 2016.

Finance expenses, net were $10,000 in the three months ended September 30, 2017, compared to $61,000 in finance income in the same period in 2016.

Net loss was $2.4 million in the three months ended September 30, 2017, compared to $1.7 million in the same period in 2016.

Non-GAAP net loss was $2.0 million in the three months ended September 30, 2017, compared to $1.4 million in the same period in 2016.

Cash, cash equivalents and short-term bank deposits totaled $6.9 million at September 30, 2017, compared to $9.2 million at June

30, 2017.

Financial Results for the Nine Months Ended September 30, 2017

Research and development expenses, net were $5.4 million in the nine months ended September 30, 2017, compared to $3.9 million in the same period in 2016. The increase is primarily attributable to (1) $983,000 decrease in grant received from the IIA which was credited to research and development expenses, net and (2) $584,000 related primarily to the Company's clinical trial to support CE Marking for the C-Scan system.

General and administrative expenses were $2.5 million in the nine months ended September 30, 2017, compared to $2.8 million in the same period in 2016. The decrease was primarily due to a $372,000 decrease in share-based compensation, which was offset primarily by an increase in payroll and related expenses ($117,000).

Operating loss was $7.9 million for the nine months ended September 30, 2017, compared to $6.6 million in the same period in 2016.

Finance income, net was $80,000 in the nine months ended September 30, 2017, compared to $204,000 in the same period in 2016.

Net loss was $7.9 million in the nine months ended September 30, 2017, compared to $6.4 million in the same period in 2016.

Non-GAAP net loss was $7.1 million in the nine months ended September 30, 2017, compared to $5.4 million in the same period in 2016.

A reconciliation of GAAP results to non-GAAP results is provided below.

Net cash used in operating activities was $7.0 million in the nine months ended September 30, 2017, compared to $6.2 million in the same period in 2016.

The number of outstanding ordinary shares as of September 30, 2017, was 16,986,051.

Use of Non-GAAP Financial Results

In addition to disclosing financial results calculated in accordance with U.S. GAAP, the Company's financial results release contains Non-GAAP financial measures of net loss for the period that exclude the effects of share-based compensation and changes in royalties provision. The Company's management believes the Non-GAAP financial information provided in this release is useful to investors' understanding and assessment of the Company's on-going operations. Management also uses both GAAP and Non-GAAP information in evaluating and operating business internally and as such deemed it important to provide all this information to investors. The Non-GAAP financial measures disclosed by the Company should not be considered in isolation or as a substitute for, or superior to, financial measures calculated in accordance with GAAP, and the financial results calculated in accordance with GAAP and reconciliations to those financial statements should be carefully evaluated. Reconciliations between GAAP measures and Non-GAAP measures are provided later in this press release.

About Check-Cap

Check-Cap is a clinical-stage medical diagnostics company developing C-Scan®, the first capsule-based system 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. The C-Scan® system is currently not cleared for marketing in any jurisdiction.

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.

[Financial Tables to Follow]

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CONSOLIDATED UNAUDITED BALANCE SHEETS

(U.S. dollars in thousands, except share and per share data)

	September 30, 2017	December 31, 2016
Assets		
Current assets		
Cash and cash equivalents	6,940	11,639
Prepaid expenses and other current assets	315	242
Total current assets	7,255	11,881
Non-current assets		
Property and equipment, net	525	414
Total non-current assets	525	414
Total assets	7,780	12,295
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable and accruals		
Trade	325	393
Other	403	235
Other current liabilities	5	11
Employees and payroll accruals	890	728
Total current liabilities	1,623	1,367
Non-current liabilities		
Royalties provision	599	521
Total non-current liabilities	599	521
Shareholders' equity		
Share capital	861	771
Additional paid-in capital	55,507	52,577

Accumulated deficit	(50,810)	(42,941)
Total shareholders' equity	5,558	10,407
Total liabilities and shareholders' equity	7,780	12,295

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CONSOLIDATED UNAUDITED STATEMENTS OF OPERATIONS

(U.S. dollars in thousands, except share and per share data)

	Nine months ended September 30,		Three months ended September 30,	
	2017	**2016**	**2017**	**2016**
Research and development expenses, net	5,437	3,870	1,564	988
General and administrative expenses	2,506	2,758	810	766
Operating loss	**7,943**	**6,628**	**2,374**	**1,754**
Finance income (expenses), net	80	204	(10)	61
Loss before tax	7,863	6,424	2,384	1,693
Taxes on income	6	-	-	-
Net loss for the period	**7,869**	**6,424**	**2,384**	**1,693**
Net loss per ordinary share basic and diluted	0.46	0.47	0.13	0.11
Weighted average number of ordinary shares outstanding - basic and diluted (in thousands)	17,019	13,794	17,775	14,817

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CONSOLIDATED UNAUDITED STATEMENTS OF CASH FLOWS

(U.S. dollars in thousands, except per share data)

	Nine months ended September 30,	
	2017	**2016**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss for the period	(7,869)	(6,424)
Depreciation and amortization	115	96
Share-based compensation	657	1,053
Financial income, net	(155)	(124)

Changes in assets and liabilities items:		
Decrease (increase) in prepaid and other current assets and non-current assets	(73)	165
Increase (decrease) in trade accounts payable, accruals and other current liabilities	64	(324)
Increase (decrease) in employees and payroll accruals	162	(619)
Increase in royalties provision	78	12
Net cash used in operating activities	**(7,021)**	**(6,165)**
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(221)	(166)
Decrease in restricted deposit	-	46
Proceeds from short-term investments	-	2,811
Net cash provided by (used in) investing activities	**(221)**	**2,691**
CASH FLOWS FROM FINANCING ACTIVITIES		
Exercise of warrants into ordinary shares	82	34
Issuance of ordinary shares in RD, net of issuance expenses in an amount of $615	-	1,123
Grant of pre-funded warrants in the registered direct offering, net of issuance expenses	-	4,271
Issuance of ordinary shares in RD, net of issuance expenses in an amount of $349	2,308	-
Net cash provided by financing activities	**2,390**	**5,428**
Effect of exchange rate changes on cash and cash equivalents	153	110
Net increase (decrease) in cash and cash equivalents	(4,699)	2,064
Cash and cash equivalents at the beginning of the period	11,639	9,392
Cash and cash equivalents at the end of the period	**6,940**	**11,456**

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SUPPLEMENTAL RECONCILIATION OF GAAP TO NON-GAAP RESULTS

(U.S. dollars in thousands)

	Nine months ended September 30,		Three months ended September 30,	
	2017	**2016**	**2017**	**2016**
GAAP net loss for the period	(7,869)	(6,424)	(2,384)	(1,693)
Share-based compensation (1)	657	1,053	310	259
Changes in royalties	78	12	29	25
Non-GAAP net loss for the period	(7,134)	(5,359)	(2,045)	(1,409)
(1) Share-based compensation:				
Research and development expenses, net	182	207	108	45
General and administrative expenses	475	846	202	214
	657	1,053	310	259

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Additional assets available online: Photos (1)

http://ir.check-cap.com/2017-11-06-Check-Cap-Reports-Third-Quarter-2017-Financial-Results