



Check-Cap Reports Third Quarter 2018 Financial Results

Announced Interim Results from Post-CE Approval Study of C-Scan® Announces Update on Scheduled Initiation of U.S. Pilot Study

ISFIYA, Israel, Nov. 5, 2018 /PRNewswire/ -- [Check-Cap Ltd.](#) (the "Company" or "Check-Cap") (NASDAQ: CHEK) (NASDAQ: CHEKW), (NASDAQ: CHEKZ), a clinical-stage medical diagnostics company engaged in the development of C-Scan®, a preparation free capsule-based screening method for the prevention of colorectal cancer through the detection of precancerous polyps, announced today financial results for the third quarter and nine months ended September 30, 2018.

Recent Highlights

- Submitted an Investigational Device Exemption (IDE) to the U.S. Food and Drug Administration (FDA) that, if approved, would allow the Company to initiate a U.S. pilot study of the C-Scan system by the end of 2018, in collaboration with GE Healthcare as manufacturing partner.
- Received approval from the Israeli Ministry of Health, the Medical Device Division (AMAR) to initiate commercial sales in Israel of the C-Scan system that received CE Mark approval in January 2018.
- Announced on September 04, 2018, encouraging interim results from its ongoing post-CE approval study of C-Scan® System Version 3, demonstrating 76% sensitivity ($P=0.0038$) and 80% specificity. Final results from the study are expected in 2Q 2019.

Alex Ovadia, Chief Executive Officer of Check-Cap, stated: "Despite strong evidence that screening can decrease the incidence of colorectal cancer, the lack of patient-friendly screening options continues to present an obstacle adherence. We believe that the C-Scan system addresses all major barriers to standard screening methods, offering a screening option for those unable or unwilling to undergo colonoscopy. During the third quarter, we made significant progress toward our goal of commercializing the C-Scan system Version 3 in Israel, the EU and major markets worldwide. Most notably, we submitted an IDE to the FDA and are preparing to initiate a U.S. pilot study in collaboration with our manufacturing partner, GE Healthcare. We believe that the C-Scan system has the potential to make a meaningful impact on the rates of colorectal cancer screening and precancerous polyp detection, and we look forward to making this novel technology available to patients worldwide."

Financial Results for the Third Quarter Ended Sept. 30, 2018

Net research and development expenses were \$1.9 million in the three months ended September 30, 2018, compared to \$1.6 million in the same period in 2017. The increase is primarily attributable to a \$232,000 increase in other R&D expenses primarily associated with the Company's post CE approval study of the C-Scan system and the IDE submission to the FDA, as well as a \$52,000 decrease in grants received from the Israel Innovation Authority (IIA), which was reflected as a credit to research and development expenses.

General and administrative expenses were \$937,000 in the three months ended September 30, 2018, compared to \$810,000 in the same period in 2017. The increase was primarily due to a \$62,000 increase in professional fees and \$35,000 of expenses related our annual general meeting of shareholders which was held in September 2018.

Operating loss was \$2.8 million for the three months ended September 30, 2018, compared to \$2.4 million in the same period in 2017.

Net finance income was \$99,000 in the three months ended September 30, 2018, compared to \$10,000 in the same period in 2017.

Net loss was \$2.7 million in the three months ended September 30, 2018, compared to \$2.4 million in the same period in 2017.

Non-GAAP net loss was \$2.6 million in the three months ended September 30, 2018, compared to \$2.0 million in the same period in 2017.

Cash, cash equivalents and short-term bank deposit totaled \$17.6 million at September 30, 2018, compared to \$20.1 million at June 30, 2018.

Financial Results for the Nine Months Ended September 30, 2018

Net research and development expenses were \$5.2 million in the nine months ended September 30, 2018,

compared to \$5.4 million in the same period in 2017. The decrease is primarily attributable to a \$511,000 decrease in salaries and related expenses as a result of a reduction in head count in 2018 and a \$66,000 decrease in share-based compensation. The decrease was partially offset by a \$325,000 increase in other R&D expenses associated with the Company's post CE approval study of the C-Scan system and the IDE submission to the FDA, well as a \$52,000 decrease in grants received from the IAA, which was credited to research and development expenses.

General and administrative expenses were \$2.4 million in the nine months ended September 30, 2018, compared to \$2.5 million in the same period in 2017. The decrease was primarily due to a decrease of \$861,000 in share-based compensation, of which \$502,000 relates to reversal of expenses associated with an equity award to the Company's former CEO which was forfeited as a result of his separation from employment. The decrease was partially offset by a \$376,000 increase in salary and related expenses primarily due to a onetime payment to the Company's former CEO as a result of his separation from employment, a \$199,000 increase in professional expenses and a \$144,000 increase in other general and administrative expenses.

Operating loss was \$7.6 million for the nine months ended September 30, 2018, compared to \$7.9 million in the same period in 2017.

Net finance income was \$108,000 in the nine months ended September 30, 2018, compared to \$80,000 in the same period in 2017.

Net loss was \$7.5 million in the nine months ended September 30, 2018, compared to \$7.9 million in the same period in 2017.

Non-GAAP net loss was \$7.7 million in the nine months ended September 30, 2018, compared to \$7.1 million in the same period in 2017.

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

Net cash used in operating activities was \$7.3 million in the nine months ended September 30, 2018, compared to \$7.0 million in the same period in 2017.

The number of outstanding ordinary shares as of September 30, 2018, was 5,329,891.

[Financial Tables to Follow]

About Check-Cap

Check-Cap is a clinical-stage medical diagnostics company developing C-Scan®, an ingestible capsule-based device 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.

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 ongoing 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.

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 for the year ended December 31, 2017 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, except share and per share data)

	September 30, 2018	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	8,485	6,997
Short-term bank deposit	9,080	-
Prepaid expenses and other current assets	496	406
Total current assets	<u>18,061</u>	<u>7,403</u>
Non-current assets		
Property and equipment, net	435	503
Total non-current assets	<u>-</u>	<u>503</u>
Total assets	<u>18,496</u>	<u>7,906</u>
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable and accruals		
Trade	813	608
Other	308	347
Other current liabilities	9	5
Employees and payroll accruals	951	602
Total current liabilities	<u>2,081</u>	<u>1,562</u>
Non-current liabilities		
Royalties provision	479	439
Total non-current liabilities	<u>479</u>	<u>439</u>
Shareholders' equity		
Share capital	3,455	974
Additional paid-in capital	72,678	57,643
Accumulated deficit	(60,197)	(52,712)
Total shareholders' equity	<u>15,936</u>	<u>5,905</u>
Total liabilities and shareholders' equity	<u>18,496</u>	<u>7,906</u>

CHECK CAP LTD

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

	<u>Nine months ended</u> <u>September 30,</u>		<u>Three months ended</u> <u>September 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Research and development expenses, net	5,222	5,437	1,865	1,564
General and administrative expenses	2,372	2,506	937	810
Operating loss	7,594	7,943	2,802	2,374
Finance income (expenses), net	108	80	99	(10)
Loss before tax	7,486	7,863	2,703	2,384
Tax expenses (gains) on income	(1)	6	-	-
Net loss for the period	7,485	7,869	2,703	2,384
Net loss per ordinary share basic and diluted	2.07	5.25	0.50	1.38
Weighted average number of ordinary shares outstanding - basic and diluted (in thousands)	3,622	1,500	5,356	1,723

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

	<u>Nine months ended</u> <u>September 30,</u>	
	<u>2018</u>	<u>2017</u>
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss for the period	(7,485)	(7,869)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	118	115
Share-based compensation	(271)	657
Financial expense, net	(43)	(155)
Changes in assets and liabilities items:		
Decrease in prepaid and other current assets and non-current assets	(90)	(73)
Increase in trade accounts payable, accruals and other current liabilities	60	64
Increase in employees and payroll accruals	349	162
Increase in royalties provision	40	78
Net cash used in operating activities	(7,322)	(7,021)
CASH FLOWS FROM INVESTING ACTIVITIES		

Purchase of property and equipment	(14)	(221)
Short-term investments	(9,000)	-
Net cash used in investing activities	(9,014)	(221)
CASH FLOWS FROM FINANCING ACTIVITIES		
Exercise of pre-funded warrants into ordinary shares	4	82
Issuance of ordinary shares in the June 2017 RD Offering, net of issuance expenses in an amount of \$349	-	2,308
Issuance of ordinary shares in the 2018 Public Offering, net of issuance expenses in an amount of \$2,381	17,858	-
Net cash provided by financing activities	17,862	2,390
Effect of exchange rate changes on cash and cash equivalents	(38)	153
Net increase (decrease) in cash and cash equivalents	1,488	(4,699)
Cash and cash equivalents at the beginning of the period	6,997	11,639
Cash and cash equivalents at the end of the period	8,485	6,940

CHECK-CAP LTD.
SUPPLEMENTAL RECONCILIATION OF GAAP TO NON-GAAP RESULTS
(U.S. dollars in thousands)

	<u>Nine months ended</u>		<u>Three months ended</u>	
	<u>September 30,</u>		<u>September 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
GAAP net loss for the period	(7,485)	(7,869)	(2,703)	(2,384)
Share-based compensation (1)	(271)	657	122	310
Changes in royalties	40	78	15	29
Non-GAAP net loss for the period	(7,716)	(7,134)	(2,566)	(2,045)
(1) Share-based compensation:				
Research and development expenses, net	115	182	81	108
General and administrative expenses:				
General and administrative expenses	116	475	41	202
One time reversal of equity award to the Company's Former CEO	(502)	-	-	-
	(271)	657	122	310

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