



Check-Cap Reports Fourth Quarter and Full Year 2017 Financial Results

Announces the achievement of key validation milestones in C-Scan® system clinical and regulatory pathway

ISFIYA, Israel, April 4, 2018 /[PRNewswire](#)/ -- Check-Cap Ltd. (the "Company" or "Check-Cap") (NASDAQ: CHEK, CHEKW), a clinical stage medical diagnostics company developing a capsule-based system for preparation-free, colorectal cancer screening, today provided a corporate update and announced its financial results for the three- and twelve-month period ended December 31, 2017.

Recent Highlights

- Initiated an EU post approval study using C-Scan system Version 3 (formerly referred to as Advanced C-Scan system), which incorporates the latest algorithms and system optimization and tailors scanning of the colon to the patient's natural colonic movements to maximize the amount of the colon that is tracked and imaged, and has demonstrated significant improvement in average colon imaging coverage compared with the C-Scan version used in the multi-center clinical study that supported the Company's CE Mark approval received in January 2018.
- Reported interim clinical study of C-Scan Version 3 in March 2018 with evaluable results of 21 patients showing average colon imaging coverage of 64%, a 40% improvement over 46% average colon imaging coverage in the CE Mark study. As demonstrated in the CE Mark study, sensitivity (ability to correctly identify polyps) is strongly correlated ($R^2 = 0.98$) to the percentage of colon imaging coverage. Sensitivity was 78% ($p < 0.05$) for subjects with greater than 50% colon imaging coverage and 100% ($p < 0.05$) for subjects with greater than 70% colon imaging coverage. Specificity (ability to correctly identify lack of polyps) was consistent at around 89%.
- Entered the next phase of manufacturing collaboration with GE Healthcare ("GE"). The new phase involves GE final assembly, packaging and shipping of C-Scan capsules initially to support the Company's U.S. pilot trial. Check-Cap will supply GE with supporting calibration and final assembly methodology and equipment.
- Late breaking, oral presentation of clinical safety and performance study abstract, "Clinical Performance of a Novel X-ray Based Imaging Capsule for Colonic Screening", and presentation of "A novel capsule technology platform for specific localized colon drug delivery" poster, recognized as one of "Posters of Excellence" at the United European Gastroenterology (UEG) Week 2017 in Barcelona, Spain.
- In November and June 2017, the Company consummated two registered direct offerings of ordinary shares and concurrent private placements of warrants, with gross proceeds of \$2.5 million and \$2.69 million, respectively.
- Submitted an application in February 2018, to register the C-Scan system for marketing and sale in Israel.
- Appointed Alex Ovadia as Chief Executive Officer effective February 26, 2018. Prior to this appointment, Mr. Ovadia served as Check-Cap's Chief Operating Officer, Vice President of Research and Development and Israeli site manager since 2013.

In addition, the Company announced a 1-for-12 reverse share split of its ordinary shares, effective as of April 4, 2018. Beginning on April 4, 2018, the Company's ordinary shares will trade on the NASDAQ Capital Market on a post-reverse share split adjusted basis. At Check-Cap's extraordinary general meeting of shareholders held on April 2, 2018, the Company's shareholders approved a reverse share split at a ratio in the range of 1-for-8 to 1-for-12, the exact ratio to be determined by further action of the Company's Board of Directors ("Board"), to be effective on a date to be determined by the Board. On April 2, 2018, the Board approved a reverse split at a ratio of 1-for-12, effective as of April 4, 2018. All share and per share amounts in this release have been adjusted to reflect the reverse share split. Further, at the extraordinary general meeting of shareholders, the Company's shareholders approved an increase in the Company's authorized and registered share capital by NIS 12,500,000 and to amend the Company's Articles of Association accordingly.

Alex Ovadia, CEO of Check-Cap, stated: "We believe that 2017 was a productive year for Check-Cap, with EU regulatory submissions in September yielding a key validation of our C-Scan system and with receipt of our CE Mark approval in January 2018. We were also very pleased to initiate our EU post approval study in March 2018, using C-Scan system Version 3, which incorporates the latest algorithms and system optimization and demonstrated a significant improvement in average colon imaging coverage in an interim study." Mr. Ovadia continued, "As we enter 2018 and look beyond, we plan to continue our EU post approval study, and anticipate that we will achieve clinical performance consistent with that seen in the CE study with majority of colon imaging coverage. We intend to continue to hold productive discussions with regulatory agencies in support of the C-Scan

system Version 3 as we move toward initiation of our U.S. pilot study, which we expect to commence during the second half of 2018. We believe that successful completion of both the U.S. pilot and EU post approval studies, supported with sufficient capital, will become the key drivers in our efforts to commence the U.S. pivotal study during 2019. In parallel to our program's execution, we intend to continue to leverage our CE Mark and ISO 13485 certification through submitting an application to register the C-Scan system for marketing and sale in Israel. We are also continuing our work to develop our marketing and commercial pathways throughout 2018, while initiating discussions with potential partners, for both Israel and Europe markets."

Financial Results for the Fourth Quarter Ended December 31, 2017

Research and development expenses, net were \$1.4 million in the three months ended December 31, 2017, compared to \$1.6 million in the same period in 2016. This decrease was primarily due to a \$91,000 decrease in share-based compensation expenses, a \$256,000 decrease in bonus provision and a \$133,000 decrease in fees to subcontractors and consultants. The decrease was offset primarily by an increase of \$284,000 in other expenses.

General and administrative expenses were \$658,000 in the three months ended December 31, 2017, compared to \$813,000 in the same period in 2016. This decrease was primarily due to a \$175,000 decrease in bonus provision

Operating loss was \$2.1 million for the three months ended December 31, 2017, compared to \$2.4 million in the same period in 2016.

Finance income, net was \$156,000 in the three months ended December 31, 2017, and consisted primarily of \$168,000 of finance income (comprised of \$159,000 of changes in provision for royalties and \$9,000 in interest income on short-term deposits), offset by \$12,000 of finance expenses (comprised primarily of \$11,000 of exchange rate differences).

Net loss was \$1.9 million in the three months ended December 31, 2017, compared to \$2.4 million in the same period in 2016.

Non-GAAP net loss was \$1.5 million in the three months ended December 31, 2017, compared to \$2.3 million in the same period in 2016.

Cash, cash equivalents and short-term bank deposits totaled \$7 million at December 31, 2017.

Financial Results for the Full Year Ended December 31, 2017

Research and development expenses, net were \$6.8 million in the year ended December 31, 2017, compared to \$5.5 million in the same period in 2016. This increase was primarily due to a \$922,000 decrease in grants from the Israel Innovation Authority of the Ministry of Economy and Industry (formerly the Office of the Chief Scientist); a \$136,000 increase in fees to subcontractors and consultants and a \$382,000 increase in other research and development expenses relating to the Company's clinical trials and regulatory expenses, primarily in connection with the application for CE Mark approval for our C-Scan system and preparation for the U.S. pilot study. The increase was partially offset by a \$118,000 decrease in share-based compensation expenses

General and administrative expenses were \$3.2 million in the year ended December 31, 2017 compared to \$3.6 million in the same period in 2016. This decrease was primarily due to a \$365,000 decrease in 2017 of share-based compensation expenses, and a \$104,000 decrease in other general and administrative expenses primarily due to decreased public relation expenses.

Operating loss was \$10 million for the year ended December 31, 2017, compared to \$9.1 million in the same period in 2016.

Finance income, net was \$236,000 in the year ended December 31, 2017 compared to \$244,000 in the same period in 2016. This decrease was primarily due to a \$73,000 decrease in interest income on short-term deposits resulting from a lower average short term deposits balance in 2017, which decrease was offset primarily by a \$64,000 increase in finance income (comprised primarily of \$39,000 of exchange rate differences and \$25,000 of changes in provision for royalties).

Net loss for the year ended December 31, 2017 was \$9.8 million, compared to \$8.8 million in the same period in 2016.

Non-GAAP net loss was \$8.6 million in the year ended December 31, 2017, compared to \$7.7 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 \$9.2 million in the year ended December 31, 2017, compared to \$7.9 million in the same period in 2016.

Net cash provided by financing activities was \$4.6 million in the year ended December 31, 2017, and \$5.4 million in the year ended December 31, 2016, both as a result of proceeds from our registered direct offerings.

The number of outstanding ordinary shares as of December 31, 2017 and April 4, 2018 was approximately 1,605,434 and 1,610,620, post-reverse share split, respectively.

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, changes in royalties provision and revaluation of warrants to purchase preferred shares. 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.

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 "Forward-looking Statements" and "Risk Factors" in the Company's Annual Report on Form 20-F for its fiscal 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.

[Financial Tables to Follow]

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

	<u>December 31,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
Assets		
Current assets		
Cash and cash equivalents	6,997	11,639
Prepaid expenses and other current assets	<u>406</u>	<u>242</u>

Total current assets	<u>7,403</u>	<u>11,881</u>
Non-current assets		
Property and equipment, net	<u>503</u>	<u>414</u>
Total non-current assets	<u>503</u>	<u>414</u>
Total assets	<u>7,906</u>	<u>12,295</u>
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable and accruals		
Trade	608	393
Other	347	235
Other current liabilities	5	11
Employees and payroll accruals	<u>602</u>	<u>728</u>
Total current liabilities	<u>1,562</u>	<u>1,367</u>
Non-current liabilities		
Royalties provision	<u>439</u>	<u>521</u>
Total non-current liabilities	<u>439</u>	<u>521</u>
Shareholders' equity		
Preferred shares		
Share capital	974	771
Additional paid-in capital	57,643	52,577
Accumulated deficit	<u>(52,712)</u>	<u>(42,941)</u>
Total shareholders' equity	<u>5,905</u>	<u>10,407</u>
Total liabilities and shareholders' equity	<u>7,906</u>	<u>12,295</u>

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

	Year ended December 31,		Three months ended December 31,	
	2017	2016	2017	2016
Research and development expenses, net	6,837	5,491	1,400	1,621
General and administrative expenses	<u>3,164</u>	<u>3,571</u>	<u>658</u>	<u>813</u>
Operating loss	<u>10,001</u>	<u>9,062</u>	<u>2,058</u>	<u>2,434</u>
Finance income, net	236	244	156	40
Loss before income tax	<u>9,765</u>	<u>8,818</u>	<u>1,902</u>	<u>2,394</u>
Taxes on income	6	8	-	8
Net loss for the period	<u>9,771</u>	<u>8,826</u>	<u>1,902</u>	<u>2,402</u>
Net loss per ordinary share basic and diluted	<u>6.72</u>	<u>7.31</u>	<u>1.22</u>	<u>1.75</u>
Weighted average number of ordinary shares outstanding - basic				
and diluted (in thousands)	<u>1,455</u>	<u>1,208</u>	<u>1,562</u>	<u>1,369</u>

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

	Year ended December 31,		Three months ended December 31,	
	2017	2016	2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES				
Net loss for the period	(9,771)	(8,826)	(1,902)	(2,402)
Adjustments required to reconcile net loss to net cash used in operating activities:				
Revaluation of fair value of warrants to purchase preferred shares	-	-	-	-
Depreciation and amortization	157	130	42	34
Share-based compensation	726	1,209	69	156
Financial expenses (income), net	(165)	(56)	(10)	68
Changes in assets and liabilities items:				
Decrease (increase) in prepaid and other current assets and non-current assets	(164)	438	(91)	273
Increase (decrease) in trade accounts payable, accruals and other current liabilities	275	(252)	211	72
Increase (decrease) in employees and payroll accruals	(126)	(510)	(288)	109
Decrease in royalties provision	(82)	(56)	(160)	(68)
Net cash used in operating activities	(9,150)	(7,923)	(2,129)	(1,758)
CASH FLOWS FROM INVESTING ACTIVITIES				
Purchase of property and equipment	(231)	(166)	(10)	-
Restricted cash	-	46	-	-
Proceeds from short-term bank deposit	-	4,811	-	2,000
Net cash provided by (used in) investing activities	(231)	4,691	(10)	2,000
CASH FLOWS FROM FINANCING ACTIVITIES				
Receipt of short-term loan from bank	-	-	-	-
Repayment of short-term loan from bank	-	-	-	-
Issuance of ordinary shares upon exercise of stock options by employees	-	-	-	-
Exercise of warrants into ordinary shares	196	117	114	83
Issuance of ordinary shares in the RD offering, net of issuance expenses	4,379	5,307	2,071	(87)
Net cash provided by financing activities	4,575	5,424	2,185	(4)
Effect of exchange rate changes on cash and cash equivalents	164	55	11	(55)
Net increase (decrease) in cash and cash equivalents	(4,642)	2,247	57	183
Cash and cash equivalents at the beginning of the period	11,639	9,392	6,940	11,456

Cash and cash equivalents at the end of the period	<u>6,997</u>	<u>11,639</u>	<u>6,997</u>	<u>11,639</u>
Supplemental disclosure of non-cash flow information:				
Cashless exercise of warrants to purchase ordinary shares into ordinary shares	8	23	-	-
Purchase of property and equipment	15	8	10	8
Issuance expenses in the registered direct offering	30	47	30	-
Supplemental disclosure of cash flow information				
Cash paid for income taxes	-	8	-	8
Cash paid for interest	3	-	-	-

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

	Year ended December 31,		Three months ended December 31,	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
GAAP net loss for the period	(9,771)	(8,826)	(1,902)	(2,402)
Share-based compensation (1)	726	1,209	69	156
Changes in royalties	439	(56)	361	(68)
Financial income related to revaluation of fair value of preferred shares warrants	-	-	-	-
Non-GAAP net loss for the period	<u>(8,606)</u>	<u>(7,673)</u>	<u>(1,472)</u>	<u>(2,314)</u>
(1) Share-based compensation:				
Research and development expenses, net	116	234	(66)	27
General and administrative expenses	610	975	135	129
	<u>726</u>	<u>1,209</u>	<u>69</u>	<u>156</u>

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