

Check-Cap Reports Fourth Quarter and Fiscal Year 2016 Financial Results

ISFIYA, Israel, March 9, 2017 /PRNewswire/ -- Check-Cap Ltd. (the "Company" or "Check-Cap") (NASDAQ: CHEK, CHEKW), a clinical stage medical diagnostics company engaged in the development of an ingestible capsule for preparation-free, colorectal cancer screening, today provided a corporate update and announced its financial results for the fourth quarter and fiscal year ended December 31, 2016.

"We continue to advance our clinical and regulatory objectives through initiation in January of our trial to support CE Marking for the C-Scan® system," said Bill Densel, CEO of Check-Cap. "Submission of our CE Mark application is expected during the first half of this year, and we plan to initiate a pilot trial in the U.S. in the second half of the year. We believe that 2017 will be a pivotal year for the company."

Financial Results for the Fourth Quarter Ended December 31, 2016

Research and development expenses, net were \$1.6 million in the three months ended December 31, 2016, equal to the same period in 2015.

General and administrative expenses were \$813,000 in the three months ended December 31, 2016, compared to \$1.5 million in the same period in 2015. This decrease was primarily due to a decrease in salary and related expenses of \$246,000, a decrease in share based compensation of \$315,000 and a decrease in professional fees of \$275,000. This decrease was partially offset by an increase of \$160,000 in other general and administrative expenses.

Operating loss was \$2.4 million for the three months ended December 31, 2016, compared to \$3.1 million in the same period in 2015.

Finance income, net was \$40,000 in the three months ended December 31, 2016, compared to \$82,000 in the same period in 2015.

Net loss was \$2.4 million in the three months ended December 31, 2016, compared to \$3.0 million in the same period in 2015.

Non-GAAP net loss was \$2.3 million in the three months ended December 31, 2016, compared to \$2.4 million in the same period in 2015.

Cash, cash equivalents and short-term bank deposit totaled \$11.6 million at December 31, 2016, compared to \$13.5 million at September 30, 2016.

Financial Results for the Full Year Ended December 31, 2016

Research and development expenses, net were \$5.5 million in the year ended December 31, 2016, compared to \$5.8 million in the same period in 2015. This decrease was primarily due to a \$770,000 increase in grants from the National Authority for Technology and Innovation (NATI), formerly known as the Office of the Chief Scientist (OCS) in 2016, a \$556,000 decrease in share-based compensation, primarily due to the absence in 2016 of a \$448,000 share-based compensation expense recorded in 2015 associated with the one-time grant of options to certain members of the Company's management, and a \$368,000 decrease in fees to subcontractors and consultants in 2016 as the Company increased the number of research and development employees in 2016. The decrease in research and development expenses, net between 2016 and 2015 was partially offset by a \$1.1 million increase in salaries and related expenses as a result of the recruitment of research and development employees during the course of 2015, the related expenses for whom were fully accounted for in 2016 and a \$229,000 increase in other research and development expenses relating to the clinical trials.

General and administrative expenses were \$3.6 million in the year ended December 31, 2016 compared to \$6.6 million in the same period in 2015. This decrease was primarily due to the absence in 2016 of a \$2.0 million share-based compensation expense recorded in 2015 relating to the one-time grant of options to certain members of the Company's management and warrants to Pontifax entities, a \$419,000 decrease in salaries and related expenses, primarily due to the absence in 2016 of a \$140,000 one-time severance payment to the Company's former chief executive officer that was recorded in 2015 and a \$109,000 decrease in provision for bonuses to certain members of the Company's management in 2016, a \$715,000 decrease in professional services and other general and administrative expenses, primarily relating to a \$248,000 decrease in recruiting expenses, a \$155,000 decrease in legal fees due to our recruitment of an in-house counsel, as well as reduced rates or services of certain other professional service providers.

Operating loss was \$9.1 million for the year ended December 31, 2016, compared to \$12.5 million in the same period in 2015.

Finance income, net was \$244,000 in the year ended December 31, 2016, compared to \$173,000 in the same period in 2015.

Net loss for the year ended December 31, 2016 was \$8.8 million, compared to \$12.3 million in the same period in 2015.

Net cash used in operating activities was \$7.9 million in the year ended December 31, 2016, compared to \$8.6 million in the same period in 2015.

Net cash provided by financing activities was \$5.4 million in the year ended December 31, 2016, as a result of the Company's registered direct offering and \$22 million in the year ended December 31, 2015 as a result of the Company's IPO and concurring private placement.

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

The number of outstanding ordinary shares as of December 31, 2016 and March 7, 2017 was 15,205,075 and 15,505,364, 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. 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 Follow

CHECK-CAP LTD.

CONSOLIDATED BALANCE SHEETS

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

	<u>December 31,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
<u>Assets</u>		
Current assets		
Cash and cash equivalents	11,639	9,392
Restricted cash	-	46
Short-term bank deposit	-	4,811
Prepaid expenses and other current assets	<u>242</u>	<u>680</u>
Total current assets	<u>11,881</u>	<u>14,929</u>
Non-current assets		
Property and equipment, net	<u>414</u>	<u>369</u>
Total non-current assets	<u>414</u>	<u>369</u>
Total assets	<u>12,295</u>	<u>15,298</u>
<u>Liabilities and shareholders' equity</u>		
Current liabilities		
Accounts payable and accruals		
Trade	393	577
Other	235	245
Other current liabilities	11	13
Employees and payroll accruals	<u>728</u>	<u>1,238</u>
Total current liabilities	<u>1,367</u>	<u>2,073</u>
Non-current liabilities		
Royalties provision	<u>521</u>	<u>577</u>
Total non-current liabilities	<u>521</u>	<u>577</u>
<u>Shareholders' equity</u>		
Share capital	771	599
Additional paid-in capital	52,577	46,164
Accumulated deficit	<u>(42,941)</u>	<u>(34,115)</u>
Total shareholders' equity	<u>10,407</u>	<u>12,648</u>

Total liabilities and shareholders' equity 12,295 15,298

CHECK-CAP LTD.

CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Year ended		Three months ended	
	December 31,		December 31,	
	2016	2015	2016	2015
Research and development expenses, net	5,491	5,837	1,621	1,583
General and administrative expenses	3,571	6,626	813	1,470
Operating loss	<u>9,062</u>	<u>12,463</u>	<u>2,434</u>	<u>3,053</u>
Finance income, net	244	173	40	82
Loss before income tax	8,818	12,290	2,394	2,971
Taxes on income	8	-	8	-
Net loss for the period	<u>8,826</u>	<u>12,290</u>	<u>2,402</u>	<u>2,971</u>
Net loss per ordinary share basic and diluted	<u>0.61</u>	<u>1.06</u>	<u>0.15</u>	<u>0.22</u>
Weighted average number of ordinary shares outstanding - basic and diluted (in thousands)	<u>14,499</u>	<u>11,918</u>	<u>16,428</u>	<u>13,265</u>

CHECK-CAP LTD.

CONSOLIDATED STATEMENTS OF CASH FLOWS

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

	Year ended		Three months ended	
	December 31,		December 31,	
	2016	2015	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES				
Net loss for the period	(8,826)	(12,290)	(2,402)	(2,971)
Adjustments required to reconcile net loss to net cash used in operating activities:				
Revaluation of fair value of warrants to purchase preferred shares	-	(174)	-	-
Depreciation and amortization	130	92	34	30
Share-based compensation	1,209	3,724	156	555
Financial expenses (income), net	(56)	(11)	68	(3)
Changes in assets and liabilities items:				
Decrease (increase) in prepaid and other current assets and non-current assets	438	(563)	273	(346)
Increase (decrease) in trade accounts payable, accruals and other current liabilities	(252)	334	72	209
Increase (decrease) in employees and payroll accruals	(510)	227	109	257
Increase (decrease) in royalties provision	(56)	33	(68)	(10)
Net cash used in operating activities	<u>(7,923)</u>	<u>(8,628)</u>	<u>(1,758)</u>	<u>(2,279)</u>
CASH FLOWS FROM INVESTING ACTIVITIES				
Purchase of property and equipment	(166)	(270)	-	(63)
Restricted cash	46	-	-	-
Investment in (proceeds from) short-term bank deposit	4,811	(4,800)	2,000	1,989
Net cash provided by (used in) investing activities	<u>4,691</u>	<u>(5,070)</u>	<u>2,000</u>	<u>1,926</u>
CASH FLOWS FROM FINANCING ACTIVITIES				
Receipt of short-term loan from bank	-	1,000	-	-

Repayment of short-term loan from bank	-	(1,000)	-	-
Issuance of ordinary shares upon exercise of stock options by employees	-	16	-	-
Exercise of warrants into ordinary shares	117	29	83	-
Issuance of ordinary shares in the RD offering, net of issuance expenses	5,307	-	(87)	-
Issuance of ordinary shares in the private placement, net of issuance expenses	-	11,021	-	-
Issuance of ordinary shares in IPO, net of issuance expenses	-	10,947	-	-
Net cash provided by financing activities	5,424	22,013	(4)	-
Effect of exchange rate changes on cash and cash equivalents	55	2	(55)	2
Net increase (decrease) in cash and cash equivalents	2,247	8,317	183	(351)
Cash and cash equivalents at the beginning of the period	9,392	1,075	11,456	9,743
Cash and cash equivalents at the end of the period	11,639	9,392	11,639	9,392
Supplemental disclosure of non-cash flow information:				
Reclassification of liability warrants to equity warrants	-	233	-	-
Cashless exercise of warrants to purchase ordinary shares into ordinary shares	23	45	-	-
Conversion of preferred shares into ordinary shares	-	226	-	-
Purchase of property and equipment	8	-	8	-
Issuance expenses in the registered direct offering	47	-	-	-
Supplemental disclosure of cash flow information				
Cash paid for income taxes	8	-	8	-
Cash paid for interest	-	11	-	-

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

	Year ended		Three months ended	
	December 31,		December 31,	
	2016	2015	2016	2015
GAAP net loss for the period	(8,826)	(12,290)	(2,402)	(2,971)
Share-based compensation (1)	1,209	3,724	156	555
Changes in royalties	(56)	33	(68)	(10)
Financial income related to revaluation of fair value of preferred shares warrants	-	(174)	-	-
Non-GAAP net loss for the period	(7,673)	(8,707)	(2,314)	(2,426)
 (1) Share-based compensation:				
Research and development expenses, net	234	790	27	111
General and administrative expenses	975	2,934	129	444
	1,209	3,724	156	555

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<http://ir.check-cap.com/2017-03-09-Check-Cap-Reports-Fourth-Quarter-and-Fiscal-Year-2016-Financial-Results>