

Check-Cap Reports Second Quarter 2017 Financial Results

ISFIYA, Israel and BOSTON, Aug. 10, 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 provided a corporate update and announced its financial results for the second quarter and six months ended June 30, 2017.

"During the recent quarter, we continued to advance our ongoing clinical program and are on track to submit C-Scan® for CE Marking this summer," said Bill Densel, CEO of Check-Cap. "Following the achievement of the initial milestone of our ongoing collaboration, Check-Cap, along with our collaborator GE Healthcare, has received approval of a conditional grant to support a joint development project for C-Scan® from the Israel-U.S. Binational Industrial Research and Development Foundation. This project aims to develop a high volume manufacturing and distribution process of C-Scan® to the U.S. market."

Recent Highlights:

- Check-Cap and GE Healthcare received approval of a \$1 million conditional grant from the Israel-U.S. Binational Industrial Research and Development Foundation (BIRD). The grant will support development of a high-volume manufacturing process for the C-Scan® system's X-ray source and capsule assembly, and establishing a unique product distribution process for a pilot clinical trial in the U.S. The award of the grant is conditioned, among other things, on submission of an application for CE Marking of the C-Scan® system.
- On June 2, 2017 the Company closed a registered direct offering of ordinary shares and a concurrent private placement with gross proceeds of \$2.69 million with a single health-care focused institutional investor.

Financial Results for the Second Quarter Ended June 30, 2017

Research and development expenses, net were \$2.0 million in the three months ended June 30, 2017, compared to \$1.1 million in the same period in 2016. The increase is primarily attributable to (1) \$561,000 grant received from the Israel Innovation Authority (the "IIA") which was credited to research and development expenses, net during the second quarter of 2016 and (2) \$355,000 related primarily to the Company's clinical trial to support CE Marking for the C-Scan® system.

General and administrative expenses were \$0.8 million in the three months ended June 30, 2017, compared to \$0.9 million in the same period in 2016. The decrease was primarily due to a \$190,000 decrease in share-based compensation, which was offset primarily by an increase in payroll related expenses (\$103,000).

Operating loss was \$2.8 million for the three months ended June 30, 2017, compared to \$2.0 million in the same period in 2016.

Finance expenses, net were \$20,000 in the three months ended June 30, 2017, compared to \$15,000 in the same period in 2016.

Net loss was \$2.8 million in the three months ended June 30, 2017, compared to \$2.0 million in the same period in 2016.

Non-GAAP net loss was \$2.7 million in the three months ended June 30, 2017, compared to \$1.6 million in the same period in 2016.

Cash, cash equivalents and short-term bank deposit totaled \$9.2 million at June 30, 2017, compared to \$9.4 million at March 31, 2017. Check-Cap's cash balance as of June 30, 2017 includes the net proceeds from the June 2, 2017 registered direct offering and concurrent private placement.

Financial Results for the Six Months Ended June 30, 2017

Research and development expenses, net were \$3.9 million in the six months ended June 30, 2017, compared to \$2.9 million in the same period in 2016. The increase is primarily attributable to (1) \$651,000 grant received from the IIA which was credited to research and development expenses, net during the six months ended June 30, 2016 and (2) \$428,000 related primarily to the Company's clinical trial to support CE Marking for the C-Scan® system. This increase was partially offset by a \$88,000 decrease in share-based compensation.

General and administrative expenses were \$1.7 million in the six months ended June 30, 2017, compared to \$2.0 million in the same period in 2016. The decrease was primarily due to a \$360,000 decrease in share-based compensation, which was offset primarily by an increase in payroll related expenses (\$69,000).

Operating loss was \$5.6 million for the six months ended June 30, 2017, compared to \$4.9 million in the same period in 2016.

Finance income, net was \$90,000 in the six months ended June 30, 2017, compared to \$143,000 in the same period in 2016.

Net loss was \$5.5 million in the six months ended June 30, 2017, compared to \$4.7 million in the same period in 2016.

Non-GAAP net loss was \$5.1 million in the six months ended June 30, 2017, compared to \$4.0 million in the same period in 2016.

Net cash used in operating activities was \$5.0 million in the six months ended June 30, 2017, compared to \$4.8 million in the same period in 2016.

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

The number of outstanding ordinary shares as of June 30, 2017, was 16,979,845, this number includes the 1,349,500 ordinary shares that were issued in the June 2, 2017 registered direct offering.

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)

	<u>June 30,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
Assets		
Current assets		
Cash and cash equivalents	9,152	11,639
Prepaid expenses and other current assets	424	242
Total current assets	<u>9,576</u>	<u>11,881</u>
Non-current assets		
Property and equipment, net	526	414
Total non-current assets	<u>526</u>	<u>414</u>

Total assets	<u>10,102</u>	<u>12,295</u>
<u>Liabilities and shareholders' equity</u>		
Current liabilities		
Accounts payable and accruals		
Trade	549	393
Other	389	235
Other current liabilities	11	11
Employees and payroll accruals	<u>951</u>	<u>728</u>
Total current liabilities	<u>1,900</u>	<u>1,367</u>
Non-current liabilities		
Royalties provision	<u>570</u>	<u>521</u>
Total non-current liabilities	<u>570</u>	<u>521</u>
<u>Shareholders' equity</u>		
Share capital	861	771
Additional paid-in capital	55,198	52,577
Accumulated deficit	<u>(48,427)</u>	<u>(42,941)</u>
Total shareholders' equity	<u>7,632</u>	<u>10,407</u>
Total liabilities and shareholders' equity	<u>10,102</u>	<u>12,295</u>

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

	<u>Six months ended June 30,</u>		<u>Three months ended June 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Research and development expenses, net	3,874	2,883	1,997	1,081
General and administrative expenses	<u>1,696</u>	<u>1,992</u>	<u>810</u>	<u>894</u>
Operating loss	<u>5,570</u>	<u>4,875</u>	<u>2,807</u>	<u>1,975</u>
Finance income (expenses), net	<u>90</u>	<u>143</u>	<u>(20)</u>	<u>(15)</u>
Loss before tax	5,480	4,732	2,827	1,990
Taxes on income	<u>6</u>	<u>-</u>	<u>3</u>	<u>-</u>
Net loss for the period	<u>5,486</u>	<u>4,732</u>	<u>2,830</u>	<u>1,990</u>
Net loss per ordinary share basic and diluted	<u>0.33</u>	<u>0.36</u>	<u>0.17</u>	<u>0.15</u>
Weighted average number of ordinary shares outstanding - basic and diluted (in thousands)	<u>16,635</u>	<u>13,277</u>	<u>16,840</u>	<u>13,274</u>

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

Six months ended	
June 30,	
2017	2016

CASH FLOWS FROM OPERATING ACTIVITIES

Net loss for the period	(5,486)	(4,732)
Depreciation and amortization	73	63
Share-based compensation	347	794
Financial income, net	(158)	(64)
Changes in assets and liabilities items:		
Decrease in prepaid and other current assets and non-current assets	(182)	(219)
Increase (decrease) in trade accounts payable, accruals and other current liabilities	107	(93)
Increase (decrease) in employees and payroll accruals	223	(535)
Increase (decrease) in royalties provision	49	(13)
Net cash used in operating activities	(5,027)	(4,799)

CASH FLOWS FROM INVESTING ACTIVITIES

Purchase of property and equipment	(81)	(79)
Decrease in restricted deposit	-	46
Proceeds from short-term investments	-	3,811
Net cash provided by (used in) investing activities	(81)	3,778

CASH FLOWS FROM FINANCING ACTIVITIES

Exercise of warrants into ordinary shares	82	5
Issuance of ordinary shares in RD 2017, net of issuance expenses in an amount of \$349	2,380	-
Net cash provided by financing activities	2,462	5

Effect of exchange rate changes on cash and cash equivalents

Net decrease in cash and cash equivalents	(2,487)	(955)
Cash and cash equivalents at the beginning of the period	11,639	9,392
Cash and cash equivalents at the end of the period	9,152	8,437

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SUPPLEMENTAL RECONCILIATION OF GAAP TO NON-GAAP RESULTS

(U.S. dollars in thousands)

	<u>Six months ended June 30,</u>		<u>Three months ended June 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
GAAP net loss for the period	(5,486)	(4,732)	(2,830)	(1,990)
Share-based compensation (1)	347	794	133	358
Changes in royalties	49	(13)	25	11
Non-GAAP net loss for the period	(5,090)	(3,951)	(2,672)	(1,621)
(1) Share-based compensation:				
Research and development expenses, net	75	162	31	66
General and administrative expenses	272	632	102	292
	347	794	133	358

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<http://ir.check-cap.com/2017-08-10-Check-Cap-Reports-Second-Quarter-2017-Financial-Results>