



Check-Cap Reports Third Quarter 2016 Financial Results

ISFIYA, Israel, Nov. 16, 2016 /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 third quarter and nine months ended September 30, 2016.

"During the past quarter, we continued to advance our ongoing clinical program and the optimization of the Check-Cap System, while executing on additional corporate priorities," said Bill Densel, CEO of Check-Cap. "Recently, additional clinical data related to safety, capsule transit, and capsule correlation to colonoscopic findings were presented at leading gastroenterology professional society meetings in the United States and Europe, and we remain on track to file a CE Mark submission in the first half of 2017."

Recent Highlights:

- Preliminary data demonstrating safety, polyp identification and location in clinical studies evaluating the Company's non-invasive system for preparation-free examination of the colon were presented at the American College of Gastroenterology (ACG) Annual Scientific Meeting and the United European Gastroenterology Week (UEGW).

Financial Results for the Third Quarter Ended September 30, 2016

Research and development expenses, net were \$1 million in the three months ended September 30, 2016, compared to \$1.6 million in the same period in 2015. This decrease was primarily due to a \$536,000 increase in participation of the Office of Chief Scientist (OCS) (pro-rated credited to R&D expenses), and a \$123,000 decrease in subcontractors and materials. This decrease was partially offset by an increase of \$78,000 in salary and related expenses and \$28,000 increase in cost of registration of patents.

General and administrative expenses were \$0.8 million in the three months ended September 30, 2016, compared to \$1.1 million in the same period in 2015. This decrease was primarily due to a decrease in personnel related cost of \$485,000, a decrease in share based compensation of \$158,000 and a decrease in professional fees of \$95,000. This decrease was partially offset by an increase of \$48,000 in facility cost and an increase of \$69,000 in other general and administrative expenses.

Operating loss was \$1.8 million for the three months ended September 30, 2016, compared to \$3 million in the same period in 2015.

Finance income, net was \$61,000 in the three months ended September 30, 2016, and consisted primarily of \$88,000 of finance income (comprised of \$54,000 in exchange rate differences and \$34,000 in interest income on short-term deposits) offset by \$27,000 of finance expenses (comprised primarily of \$25,000 of changes in royalties).

Finance expenses, net was \$94,000 in the three months ended September 30, 2015, consisted primarily of \$78,000 of exchange rate differences and \$15,000 of changes in royalties.

Net loss was \$1.7 million in the three months ended September 30, 2016, compared to \$3.1 million in the same period in 2015.

Non-GAAP net loss was \$1.4 million in the three months ended September 30, 2016, compared to \$2.6 million in the same period in 2015.

Cash, cash equivalents and short-term bank deposit totaled \$13.5 million at September 30, 2016, compared to \$9.4 million at June 30, 2016. Check-Cap's cash balance as of September 30, 2016 included - net proceeds from our August 2016 registered direct offering, and grants received from the OCS amounting to \$845,000 (of a total \$1.25 million approved grant).

Financial Results for the Nine Months Ended September 30, 2016

Research and development expenses, net were \$3.9 million in the nine months ended September 30, 2016, compared to \$4.3 million in the same period in 2015. This decrease was primarily due to a \$1.1 million increase in participation of the OCS (pro-rated credited to R&D expenses) and a decrease of \$472,000 in share-based compensation and a \$103,000 decrease in materials. This decrease was partially offset by an increase of \$1.2 million in salary and related expenses and a \$124,000 increase in the cost of registration of patents, depreciation and other research and development expenses.

General and administrative expenses were \$2.8 million in the nine months ended September 30, 2016, compared to \$5.1 million in the same period in 2015. This decrease was primarily due to a decrease in share-based compensation of \$1.6 million, a \$619,000 decrease in personnel related expenses and a \$160,000 decrease in professional fees and other general and administrative related expenses. This decrease was partially offset by an increase of \$71,000 in facility cost.

Operating loss was \$6.6 million for the nine months ended September 30, 2016, compared to \$9.4 million in the same period in 2015.

Finance income, net was \$204,000 in the nine months ended September 30, 2016, and consisted primarily of \$222,000 of finance income (comprised of \$117,000 in exchange rate differences and \$105,000 of interest income on short-term deposits) and \$18,000 of finance expenses (comprised primarily of \$12,000 of changes in royalties and \$5,000 bank fees).

Finance income, net was \$91,000 in the nine months ended September 30, 2015, and consisted primarily of \$176,000 of finance income (comprised primarily of \$174,000 in revaluation of fair value of preferred shares warrants) and \$85,000 of finance expenses (comprised of \$42,000 of changes in royalties and \$43,000 of interest expenses and bank fees).

Net loss was \$6.4 million in the nine months ended September 30, 2016, compared to \$9.3 million in the same period in 2015.

Non-GAAP net loss was \$5.4 million in the nine months ended September 30, 2016, compared to \$6.3 million in the same period in 2015.

Net cash used in operating activities was \$6.2 million in the nine months ended September 30, 2016, compared to \$6.3 million in the same period in 2015.

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

The number of outstanding ordinary shares as of September 30, 2016 and October 31, 2016 was 13,555,794 and 14,455,075, 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 the world's first ingestible capsule system for preparation-free, minimally-invasive colorectal cancer screening.

The capsule utilizes innovative ultra-low dose X-ray and wireless communication technologies to scan the inside of the colon as it moves naturally, while the patient follows his or her normal daily routine. After passage, the system generates a 3D map of the inner surface of the colon which enables detection of polyps and cancer. Designed to increase the willingness of individuals to participate in recommended colorectal cancer screening, the Check-Cap system addresses many frequently-cited barriers, including laxative bowel preparation, invasiveness, and sedation. The Check-Cap 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

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

	September 30, 2016	December 31, 2015
Assets		
Current assets		
Cash and cash equivalents	11,456	9,392
Restricted cash	-	46
Short-term investments	2,014	4,811
Prepaid expenses and other current assets	515	680
Total current assets	13,985	14,929
Non-current assets		
Property and equipment, net	439	369
Total non-current assets	439	369
Total assets	14,424	15,298
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable and accruals		
Trade	513	577
Other	136	245
Other current liabilities	11	13
Employees and payroll accruals	619	1,238
Total current liabilities	1,279	2,073
Non-current liabilities		
Royalties provision	589	577
Total non-current liabilities	589	577
Shareholders' equity		
Share capital	689	599
Ordinary share of NIS 0.2 par value-Authorized: 57,500,000 shares at December 31, 2015 and September 30, 2016; Issued and outstanding: 11,811,709 and 13,555,794 shares at December 31, 2015 and September 30, 2016, respectively		
Additional paid-in capital	52,406	46,164
Accumulated deficit	(40,539)	(34,115)
Total shareholders' equity	12,556	12,648
Total liabilities and shareholders' equity	14,424	15,298

CHECK CAP LTD
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,	
	2016	2015	2016	2015
Research and development expenses, net	3,870	4,301	988	1,603
General and administrative expenses	2,758	5,109	766	1,410
Operating loss	6,628	9,410	1,754	3,013
Finance income (expenses), net	204	91	61	(94)
Net loss for the period	6,424	9,319	1,693	3,107
Loss per ordinary share (in USD) Basic and diluted	0.47	0.81	0.11	0.23
Weighted average number of ordinary shares				

outstanding - basic and diluted (in thousands)	<u>13,794</u>	<u>11,438</u>	<u>14,817</u>	<u>13,276</u>
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CHECK CAP LTD
CONSOLIDATED UNAUDITED STATEMENTS OF CASH FLOWS
(U.S. dollars in thousands, except share and per share data)

	Nine months ended September 30,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss for the period	(6,424)	(9,319)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Revaluation of fair value of warrants to purchase preferred share	-	(174)
Depreciation and amortization	96	62
Share-based compensation	1,053	3,169
Financial income, net	(124)	-
Changes in assets and liabilities items:		
Decrease (increase) in prepaid and other current assets and non-current assets	165	(217)
Increase (decrease) in trade accounts payable, accruals and other current liabilities	(324)	129
Decrease in employees and payroll accruals	(619)	(31)
Increase in royalties provision	12	42
Net cash used in operating activities	(6,165)	(6,339)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(166)	(206)
Decrease in restricted deposit	46	-
Proceeds from (investment in) short-term bank deposits, net	2,811	(6,800)
Net cash provided by (used in) investing activities	<u>2,691</u>	<u>(7,006)</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	34	29
Issuance of ordinary shares in the IPO, net of issuance expenses	-	10,947
Issuance of ordinary shares in the private placement, net of issuance expenses	-	11,021
Issuance of ordinary shares in the registered direct offering, net of issuance expenses	1,123	-
Grant of pre-funded warrants in the registered direct offering, net of issuance expenses	4,271	-
Net cash provided by financing activities	<u>5,428</u>	<u>22,013</u>
Effect of exchange rate changes on cash and cash equivalents	110	-
Net increase in cash and cash equivalents	<u>2,064</u>	<u>8,668</u>
Cash and cash equivalents at the beginning of the period	9,392	1,075
Cash and cash equivalents at the end of the period	<u>11,456</u>	<u>9,743</u>
Non Cash financing activities :		
Issuance expenses in the registered direct offering	<u>149</u>	<u>-</u>

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

Nine months ended **Three months ended**

	September 30,		September 30,	
	2016	2015	2016	2015
GAAP net loss for the period	(6,424)	(9,319)	(1,693)	(3,107)
Share-based compensation (1)	1,053	3,169	259	480
Changes in royalties	12	42	25	15
Financial income related to revaluation of fair value of preferred shares warrants	-	(174)	-	-
Non-GAAP net loss for the period	(5,359)	(6,282)	(1,409)	(2,612)
(1) Share-based compensation:				
Research and development expenses, net	207	679	45	108
General and administrative expenses	846	2,490	214	372
	<u>1,053</u>	<u>3,169</u>	<u>259</u>	<u>480</u>

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