



Check-Cap Reports Second Quarter 2016 Financial Results

ISFIYA, Israel, Aug. 15, 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 second quarter and six months ended June 30, 2016.

"We are encouraged with the progress made in recent months in advancing both the Check Cap System and other key corporate objectives," said Bill Densel, CEO of Check-Cap. "The recent registered direct financing and grant by the Israeli Office of the Chief Scientist furnishes us with financial flexibility which we believe provides us with funding through the end of 2017 for our ongoing clinical program and U.S. pilot study. We are currently on target to submit the Check Cap System for CE Marking in the first half of 2017, and remain focused on bringing our system to market."

Recent Highlights:

- The Company closed a registered direct offering of ordinary shares and pre-paid warrants with gross proceeds of \$5.9 million with a single health-care focused institutional investor.
- The Company entered into a strategic relationship with GE Healthcare to develop and validate high-volume manufacturing for X-ray source production and assembly into Check-Cap's capsule. Upon successful completion, the parties may discuss collaboration on execution of a high-volume manufacturing facility and distribution of the Check-Cap system.
- The Company received an award of a grant in the amount of NIS 4.8 million (or approximately \$1.25 million) for 2016 from the Israeli Office of the Chief Scientist (the "OCS").
- The Company was granted two new patents, the first in the US and the second in Europe that broaden the intellectual property position covering its core X-ray technology. These latest additions build on an existing portfolio which includes 21 granted patents, 2 allowed patents and 35 pending patent applications.

Financial Results for the Second Quarter Ended June 30, 2016

Research and development expenses, net were \$1.1 million in the three months ended June 30, 2016, compared to \$1.4 million in the same period in 2015. This decrease was primarily due to a \$561,000 increase in participation of the OCS (pro-rated credited to R&D expenses), a \$119,000 decrease in subcontractors and materials and \$50,000 decrease in share based compensation. This decrease was partially offset by an increase of \$423,000 in salary and related expenses.

General and administrative expenses were \$0.9 million in the three months ended June 30, 2016, compared to \$1.2 million in the same period in 2015. This decrease was primarily due to a decrease in personnel related cost of \$139,000 and other general and administrative expenses of \$107,000.

Operating loss was \$2.0 million for the three months ended June 30, 2016, compared to \$2.6 million in the same period in 2015.

Finance expenses, net were \$15,000 in the three months ended June 30, 2016, consisted primarily of \$29,000 finance expenses as a result of exchange rate differences, compared to finance income, net of \$132,000 in the same period in 2015, consisted primarily of \$154,000 finance income as a result of exchange rate differences.

Net loss was \$2.0 million in the three months ended June 30, 2016, compared to \$2.4 million in the same period in 2015.

Non-GAAP net loss was \$1.6 million in the three months ended June 30, 2016, compared to \$2.0 million in the same period in 2015.

Cash, cash equivalents and short-term bank deposit totaled \$9.4 million at June 30, 2016, compared to \$11.7 million at March 31, 2016. Check-Cap's cash balance as of June 30, 2016 does not include the grant from the OCS or net proceeds from the registered direct offering.

Financial Results for the Six Months Ended June 30, 2016

Research and development expenses, net were \$2.9 million in the six months ended June 30, 2016, compared to \$2.7 million in the same period in 2015. This increase was primarily due to the progress made in the development of the Check-Cap system and to ongoing clinical trial expenses, including an increase in salaries and related expenses of \$1.1 million due to increased headcount and a \$81,000 increase in other research and development expenses. This increase was partially offset by a decrease of \$409,000 in share-based compensation and a \$602,000 increase in participation of the OCS (pro-rated credited to R&D expenses).

General and administrative expenses were \$2.0 million in the six months ended June 30, 2016, compared to \$3.7 million in the same period in 2015. This decrease was primarily due to a decrease in share-based compensation of \$1.5 million, a \$131,000 decrease in personnel related expenses and a \$79,000 decrease in other general and administrative related expenses.

Operating loss was \$4.9 million for the six months ended June 30, 2016, compared to \$6.4 million in the same period in 2015.

Finance income, net was \$143,000 in the six months ended June 30, 2016, compared to \$186,000 in the same period in 2015.

Net loss was \$4.7 million in the six months ended June 30, 2016, compared to \$6.2 million in the same period in 2015.

Non-GAAP net loss was \$4.0 million in the six months ended June 30, 2016, compared to \$3.7 million in the same period in 2015.

Net cash used in operating activities was \$4.8 million in the six months ended June 30, 2016, compared to \$3.8 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 June 30, 2016 was 12,254,479. This number does not include the ordinary shares that were issued in the 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, 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 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, less-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 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)

	<u>June 30,</u> <u>2016</u>	<u>December 31</u> <u>2015</u>
Assets		
Current assets		

Restricted cash	8,437	46
Short-term investments	1,003	4,811
Prepaid expenses and other current assets	899	680
Total current assets	10,339	14,927
Non-current assets		
Property and equipment, net	385	369
Total non-current assets	385	369
Total assets	10,724	15,296
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable and accruals		
Trade	491	577
Other	239	245
Other current liabilities	12	13
Employees and payroll accruals	703	1,238
Total current liabilities	1,445	2,073
Non-current liabilities		
Royalties provision	564	571
Total non-current liabilities	564	571
Shareholders' equity		
Share capital	623	599
Ordinary share of NIS 0.2 par value-Authorized: 57,500,000 shares at December 31, 2015 and June 30, 2016; Issued and outstanding: 11,811,709 and 12,254,479 shares at December 31, 2015 and June 30, 2016, respectively		
Additional paid-in capital	46,939	46,164
Accumulated deficit	(38,847)	(34,115)
Total shareholders' equity	8,715	12,648
Total liabilities and shareholders' equity	10,724	15,296

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

	Six months ended June 30,		Three months ended June 30	
	2016	2015	2016	2015
Research and development expenses, net	2,883	2,697	1,081	1,375
General and administrative expenses	1,992	3,700	894	1,193
Operating loss	4,875	6,397	1,975	2,568
Finance income (expenses), net	143	186	(15)	132
Net loss for the period	4,732	6,211	1,990	2,436
Loss per ordinary share (in USD) Basic and diluted	0.36	0.62	0.15	0.18
Weighted average number of ordinary shares outstanding - basic and diluted (in thousands)	13,277	10,503	13,274	13,266

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

	Six months ended June 30,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss for the period	(4,732)	(6,211)
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	63	38
Share-based compensation	794	2,690
Financial income, net	(64)	93
Changes in assets and liabilities items:		
Decrease in prepaid and other current assets and non-current assets	(219)	(206)
Increase (decrease) in trade accounts payable, accruals and other current liabilities	(93)	298
Decrease in employees and payroll accruals	(535)	(363)
Increase (decrease) in royalties provision	(13)	28
Net cash used in operating activities	(4,799)	(3,807)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(79)	(105)
Decrease in restricted deposit	46	-
proceeds from short-term bank deposit, net	3,811	-
Net cash provided by (used in) investing activities	3,778	(105)
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	5	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
Net cash provided by financing activities	5	22,013
Effect of exchange rate changes on cash and cash equivalents	61	-
Net increase (decrease) in cash and cash equivalents	(955)	18,008
Cash and cash equivalents at the beginning of the period	9,392	1,075
Cash and cash equivalents at the end of the period	8,437	19,083

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

	Six months ended June 30,		Three months ended June 30	
	2016	2015	2016	2015
GAAP net loss for the period	(4,732)	(6,211)	(1,990)	(2,436)
Share-based compensation (1)	794	2,690	358	423
Changes in royalties	(13)	28	11	21
Financial income related to revaluation of fair value of preferred shares warrants	-	(174)	-	-
Non-GAAP net loss for the period	(3,951)	(3,667)	(1,621)	(1,992)
(1) Share-based compensation:				
Research and development expenses, net	162	572	66	116
General and administrative expenses	632	2,118	292	307
	794	2,690	358	423

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