

Check-Cap Reports First Quarter 2016 Financial Results

ISFIYA, Israel, May 19, 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 three months ended March 31, 2016.

"Over the past several months, we have made progress towards preparing the Check-Cap system for CE Mark submission, which we expect to submit in the first half of 2017. The revised timeline reflects our current estimate to finalize the optimization of our system and validate its performance in our ongoing multi-center clinical study," said Bill Densel, CEO of Check-Cap. "We look forward to our upcoming podium presentation at Digestive Disease Week 2016."

Financial Results for the First Quarter Ended March 31, 2016

Research and development expenses, net were \$1.8 million in the three months ended March 31, 2016, compared to \$1.3 million in the same period in 2015. This increase was primarily due to the progress made in the development of the Check-Cap imaging system and to ongoing clinical trial expenses. This increase was partially offset, primarily by a decrease in share-based compensation (\$360,000).

General and administrative expenses were \$1.1 million in the three months ended March 31, 2016, compared to \$2.5 million in the same period in 2015. This decrease was primarily due to a decrease in share-based compensation (\$1.5 million). This decrease was partially offset, primarily by an increase in salaries and related expenses (\$182,000).

Operating loss was \$2.9 million in the three months ended March 31, 2016, compared to an operating loss of \$3.8 million in the same period in 2015.

Finance income, net was \$158,000 in the three months ended March 31, 2016, compared to \$54,000 in the same period in 2015.

Net loss was \$2.7 million in the three months ended March 31, 2016, compared to \$3.8 million in the same period in 2015.

Non-GAAP net loss, as defined below, was \$2.3 million in the three months ended March 31, 2016, compared to \$1.7 million in the same period in 2015.

Cash, cash equivalents and short-term bank deposits totaled \$11.7 million as of March 31, 2016, compared with \$14.2 million as of December 31, 2015.

Net cash used in operating activities was \$2.5 million in the three months ended March 31, 2016, compared to \$2.6 million in the same period in 2015.

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 first system for preparation-free scanning and imaging of the inner colon to identify precancerous polyps and cancers while being less invasive the traditional procedures. The Company is developing an ingestible capsule that utilizes proprietary, ultra-low-dose.)

ray technology to safely generate high-resolution, 3-dimensional imagery of the interior of the colon. Without requiring bowel preparation or diet and activity modifications, Check-Cap's system is designed to increase patient acceptance and adherence to colorectal cancer screening recommendations. 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)

	March 31, 2016	December 31, 2015
<u>Assets</u>		
Current assets		
Cash and cash equivalents	8,707	9,392
Restricted cash	46	46
Short-term investments	3,000	4,811 680
Prepaid expenses and other current assets Total current assets	648 12,401	14,929
Total current assets	12,401	14,929
Property and equipment, net	380	369
Total assets	12,781	15,298
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable and accruals Trade	558	577
Other	282	245
Other current liabilities	13	13
Employees and payroll accruals	1,027	1,238
Total current liabilities	1,880	2,073
Royalties provision	553	577
Shareholders' equity		
Share capital	620	599
Additional paid-in capital	46,585	46,164
Accumulated deficit	(36,857)	(34,115)
Total shareholders' equity	10,348	12,648

CHECK-CAP LTD. CONSOLIDATED UNAUDITED STATEMENTS OF OPERATIONS

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

	Three months ended March 31,	
	2016	2015
Research and development expenses, net General and administrative expenses Operating loss	1,802 1,098 2,900	1,322 2,507 3,829
Finance income, net	158	54
Net loss for the period	2,742	3,775
Net loss per ordinary share basic and diluted	0.21	0.52
Weighted average number of ordinary shares outstanding - basic and diluted (in thousands)	13,279	7,822

CHECK-CAP LTD. CONSOLIDATED UNAUDITED STATEMENTS OF CASH FLOWS

(U.S. dollars in thousands)

	Three months ended March 31,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss for the period	(2,742)	(3,775)
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	31	19
Share-based compensation	436	2,267
Changes in assets and liabilities items:		
Decrease (increase) in prepaid and other current assets and non-current assets	32	(495)
Increase (decrease) in trade accounts payable, accruals and other current liabilities	18	(88)
Decrease in employees and payroll accruals	(211)	(362)

ncrease (decrease) in royalties provision Net cash used in operating activities	(2,480)	(2,601)
CASH FLOWS FROM INVESTING ACTIVITIES Purchase of property and equipment Proceeds from short-term investments Net cash provided by (used in) investing activities	(42) 1,811 1,769	(19)
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	- - - 6	1,000 (1,000) 16 20
Issuance of ordinary shares in the IPO, net of issuance expenses Issuance of ordinary shares in the private placement, net of	-	10,329
issuance expenses Net cash provided by financing activities	6	11,021 21,386
Effect of exchange rate changes on cash and cash equivalents	-	(1)
Net increase (decrease) in cash and cash equivalents Cash and cash equivalents at the beginning of the period Cash and cash equivalents at the end of the period	(685) 9,392 8,707	18,765 1,075 19,840

CHECK-CAP LTD. SUPPLEMENTAL RECONCILIATION OF GAAP TO NON-GAAP RESULTS

(U.S. dollars in thousands)

	Three months ended March 31,	
	2016	2015
GAAP net loss for the period	(2,742)	(3,775)
Share-based compensation (1)	436	2,267
Changes in royalties	(24)	7
Financial income related to revaluation of fair value of preferred		
shares		
warrants		(174)
Non-GAAP net loss for the period	(2,330)	(1,675)
(1) Share-based compensation:		
Research and development expenses, net	96	456
General and administrative expenses	340	1,811
·	436	2,267

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SOURCE Check-Cap Ltd.

https://ir.check-cap.com/2016-05-19-Check-Cap-Reports-First-Quarter-2016-Financial-Results