



Check-Cap Reports Fourth Quarter and Full Year 2015 Financial Results

ISFIYA, Israel, March 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 three-and twelve-month period ended December 31, 2015.

"We are pleased to report that Check-Cap realized several key accomplishments in 2015, including the completion of our initial public offering ("IPO"), the advancement of our multi-center clinical study, and the achievement of key product development milestones. Published preliminary data from our study showed safe passage of the capsule and demonstrated the ability of our system to reconstruct the human colon and to identify polyps, as validated by subsequent colonoscopy, without the need for bowel preparation," said Bill Densel, CEO of Check-Cap. "Upon completion of our multi-center clinical study, we anticipate submitting for CE Mark registration in the second half 2016, and look forward to continuing our progress towards commercializing the first preparation-free system capable of examining the inner lining of the colon for precancerous polyps and cancer."

Adoption of U.S. Generally Accepted Accounting Principles ("U.S. GAAP")

The Company decided to adopt U.S. GAAP for the first time in fiscal year 2015. The Company's consolidated financial statements for the three and twelve month periods ended December 31, 2015 are presented in accordance with U.S. GAAP and the Company has recast the comparative amounts included in its financial statements to U.S. GAAP. In prior years the Company prepared the financial reports in accordance with International Financial Reporting Standards ("IFRS").

The Company elected to use U.S. GAAP to increase transparency and comparability of its financial reports and facilitate research and analysis by shareholders, analysts and other participants in the U.S.

Financial Results for the Fourth Quarter Ended December 31, 2015

Research and development expenses, net were \$1.6 million in the three months ended December 31, 2015, compared to \$833,000 in the same period in 2014. This increase was primarily due to the progress made in the development of the Check-Cap imaging system and to ongoing clinical trial expenses.

General and administrative expenses were \$1.5 million in the three months ended December 31, 2015, compared to \$837,000 in the same period in 2014. This increase was primarily due to an increase in share-based compensation (\$244,000), one-time severance package to the Company's former CEO (\$140,000) and an increase in professional expenses and customary costs associated with being a publicly-traded company.

As a result of the increase in research and development expenses, net, as well as the increase in general and administrative expenses, the Company's operating loss was \$3.1 million for the three months ended December 31, 2015, compared to \$1.7 million in the same period in 2014.

Finance income, net was \$82,000 in the three months ended December 31, 2015, compared to \$1.5 million in the same period in 2014. The Company's finance income in the three months ended December 31, 2014, net was significantly affected by changes in fair value of certain warrants issued in connection with the Company's Series A and Series C rounds of financings. According to applicable accounting standards, these warrants were recorded as a financial liability, prior to the Company's IPO. Following the IPO, on February 24, 2015, these warrants were recorded as equity. The change in fair value of these warrants in the three months ended December 31, 2014 was \$1.5 million. The change in fair value of these warrants was recorded in the statement of operations as a finance income.

Net loss was \$3.0 million in the three months ended December 31, 2015, compared to \$198,000 in the same period in 2014.

Non-GAAP net loss was \$2.4 million in the three months ended December 31, 2015, compared to \$1.5 million in the same period in 2014.

Net cash used in operating activities was \$2.3 million in the three months ended December 31, 2015, compared to \$926,000 in the same period in 2014.

Financial Results for the Full Year Ended December 31, 2015

Research and development expenses, net were \$5.8 million in the year ended December 31, 2015, compared to \$2.8 million in the same period in 2014. This increase was primarily due to the progress made in the development of the Check-Cap imaging system and to ongoing clinical trial expenses.

General and administrative expenses were \$6.6 million in the year ended December 31, 2015 compared to \$1.7 million in the same period in 2014. This increase was primarily due to a \$2.7 million increase in share-based compensation, an \$878,000 increase in payroll and related expenses, and a \$1.3 million increase in professional fees and other general and administrative expenses, primarily costs associated with being a publicly-traded company.

As a result of the increase in research and development expenses, net, as well as the increase in general and administrative expenses, the Company's operating loss was \$12.5 million for the year ended December 31, 2015, compared to \$4.5 million in the same period in 2014.

Net finance income was \$173,000 in the year ended December 31, 2015, compared to \$3.9 million in the same period in 2014. The Company's finance income, net was significantly affected by changes in fair value of certain warrants issued in connection with Series D and Series C rounds of financings, as explained above, mainly in the year ended December 31, 2014. The change in fair value of these warrants during the year ended December 31, 2015 was \$174,000 compared to \$3.5 million in the same period in 2014. The change in fair value of these warrants was recorded in the statement of operations as a finance income.

Net loss for the year ended December 31, 2015 was \$12.3 million, compared to \$610,000 in the same period in 2014.

Cash, cash equivalents and short-term bank deposit totaled \$14.2 million at December 31, 2015, compared with \$1.1 million at December 31, 2014.

Net cash used in operating activities was \$8.6 million in the year ended December 31, 2015, compared to \$3.9 million in the same period in 2014. In future periods, the Company expects cash used in operating activities to increase, as it continues to advance its clinical studies.

Net cash provided by financing activities was \$22 million in the year ended December 31, 2015, as a result of the Company's IPO and concurring private placement, compared to zero in the same period in 2014.

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 than traditional procedures. The Company is developing an ingestible capsule that utilizes proprietary, ultra-low-dose X-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 BALANCE SHEETS (U.S. dollars in thousands)

	December 31, 2015	December 31, 2014
Assets		
Current assets		
Cash and cash equivalents	9,392	1,075
Restricted cash	46	46
Short-term investments	4,811	-
Prepaid expenses and other current assets	680	117
Total current assets	14,929	1,238
Non-current assets		
Property and equipment, net	369	191
Deferred issuance costs	-	1,556
Total non-current assets	369	1,747
Total assets	15,298	2,985
Liabilities and shareholders' equity (deficiency)		
Current liabilities		
Accounts payable and accruals		
Trade	577	333
Other	245	1,355
Other current liabilities	13	50
Employees and payroll accruals	1,238	1,122
Total current liabilities	2,073	2,860
Non-current liabilities		
Royalties provision	577	544
Warrants to purchase preferred shares	-	407
Total non-current liabilities	577	951
Shareholders' equity (deficiency)		
Preferred shares	-	226
Share capital	599	53
Additional paid-in capital	46,164	20,720
Accumulated deficit	(34,115)	(21,825)
Total shareholders' equity (deficiency)	12,648	(826)
Total liabilities and shareholders' equity (deficiency)	15,298	2,985

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

	Year ended December 31,		Three months ended December 31,	
	2015	2014	2015	2014
Research and development expenses, net	5,837	2,832	1,583	830
General and administrative expenses	6,626	1,703	1,470	830
Operating loss	<u>12,463</u>	<u>4,535</u>	<u>3,053</u>	<u>1,660</u>
Finance income, net	<u>173</u>	<u>3,925</u>	<u>82</u>	<u>1,470</u>
Net loss for the period	<u>12,290</u>	<u>610</u>	<u>2,971</u>	<u>190</u>
Net loss per ordinary share basic and diluted	<u>1.06</u>	<u>1.18</u>	<u>0.22</u>	<u>0.18</u>
Weighted average number of ordinary shares outstanding - basic and diluted (in thousands)	<u>11,918</u>	<u>2,181</u>	<u>13,265</u>	<u>3,880</u>

CHECK-CAP LTD.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. dollars in thousands)

	Year ended December 31,		Three months ended December 31,	
	2015	2014	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES				
Net loss for the period	(12,290)	(610)	(2,971)	(190)
Adjustments required to reconcile net loss to net cash used in operating activities:				
Revaluation of fair value of warrants to purchase preferred shares	(174)	(3,519)	-	(1,478)
Depreciation and amortization	92	78	30	20
Share-based compensation	3,724	312	555	261
Financial expenses (income), net	(11)	1	(3)	(1)
Changes in assets and liabilities items:				
Increase in prepaid and other current assets and non-current assets	(563)	(1,545)	(346)	(1,301)
Increase in trade accounts payable, accruals and other current liabilities	334	1,377	209	1,364
Increase in employees and payroll accruals	227	466	257	442
Increase (decrease) in royalties provision	33	(415)	(10)	(35)
Net cash used in operating activities	<u>(8,628)</u>	<u>(3,855)</u>	<u>(2,279)</u>	<u>(926)</u>
CASH FLOWS FROM INVESTING ACTIVITIES				
Purchase of property and equipment	(270)	(46)	(63)	-
Investment in (proceeds from) short-term bank deposit	(4,800)	-	1,989	-
Net cash provided by (used in) investing activities	<u>(5,070)</u>	<u>(46)</u>	<u>1,926</u>	<u>-</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	29	-	-	-
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	22,013	-	-	-
Effect of exchange rate changes on cash and cash equivalents	2	1	2	-
Net increase (decrease) in cash and cash equivalents	8,317	(3,900)	(351)	(925)
Cash and cash equivalents at the beginning of the period	1,075	4,975	9,743	2,000
Cash and cash equivalents at the end of the period	9,392	1,075	9,392	1,075

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

	Year ended December 31,		Three months ended December 31,	
	2015	2014	2015	2014
GAAP net loss for the period	(12,290)	(610)	(2,971)	(198)
Share-based compensation (1)	3,724	312	555	261
Changes in royalties	33	(415)	(10)	(35)
Financial income related to revaluation of fair value of preferred shares warrants	(174)	(3,519)	-	(1,478)
Non-GAAP net loss for the period	(8,707)	(4,232)	(2,426)	(1,450)
(1) Share-based compensation:				
Research and development expenses, net	790	104	111	61
General and administrative expenses	2,934	208	444	200
	3,724	312	555	261

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<https://ir.check-cap.com/2016-03-15-Check-Cap-Reports-Fourth-Quarter-and-Full-Year-2015-Financial-Results>