



Check-Cap Reports Third Quarter 2015 Financial Results

- Company to hold 2015 Annual General Meeting of Shareholders on December 1, 2015 -

ISFIYA, Israel, Oct. 22, 2015 [/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 announced its financial results for the third quarter and nine months ended September 30, 2015. The Company also announced that it will hold its 2015 Annual General Meeting of Shareholders on December 1, 2015.

"The past quarter has been productive for Check-Cap as we advanced our clinical program and continued to enroll patients in our multi-center clinical trial," said Bill Densel, CEO of Check-Cap. "Following successful completion of the trial, we anticipate filing for CE Mark registration in the first quarter of 2016."

Financial Results for the Third Quarter Ended September 30, 2015

Research and development expenses, net were \$1.6 million in the three months ended September 30, 2015 compared to \$580,000 in the same period in 2014. This increase was primarily due to an increase in clinical trial expenses.

General and administrative expenses were \$1.4 million in the three months ended September 30, 2015 compared to \$301,000 in the same period in 2014. This increase was primarily due to an increase in payroll and related expenses (\$373,000), an increase in share-based compensation expenses (\$372,000) and an increase in professional expenses and customary costs associated with being a publicly-traded company (\$188,000).

As a result of the increase in research and development expenses, net, as well as the increase in general and administrative expense the Company's operating loss was \$3.0 million for the three months ended September 30, 2015, compared to \$881,000 in the same period in 2014.

Net finance income was \$3.0 million in the three months ended September 30, 2015. The Company's finance income or expenses reflects changes in the fair value of certain warrants issued to private placement investors. These warrants are classified as a financial liability carried at fair value on the Company's income statement. The change in fair value of these warrants during the three months ended September 30, 2015 resulted in finance income of \$3.1 million for such period. Net finance income was \$589,000 in the three months ended September 30, 2014. Net finance income in the third quarter of 2014 consisted primarily of changes in royalties provisions, as further described in the Company's 2014 annual report on Form 20-F, filed with the U.S. Securities and Exchange Commission on April 29, 2015.

Net loss for the three months ended September 30, 2015 was \$48,000 compared to \$292,000 in the same period in 2014.

Non-GAAP net loss for the three months ended September 30, 2015 was \$2.6 million compared to \$841,000 in the same period in 2014. Reconciliations between GAAP measures and Non-GAAP measures are provided later in this press release.

Financial Results for the Nine Months Ended September 30, 2015

Research and development expenses, net were \$4.3 million in the nine months ended September 30, 2015 compared to \$2.2 million in the same period in 2014. This increase was primarily due to on-going clinical trial expenses.

General and administrative expenses were \$5.1 million in the nine months ended September 30, 2015 compared to \$865,000 in the same period in 2014. This increase was primarily due to an increase in payroll and related expenses (\$700,000), an increase in share-based compensation expenses (\$2.5 million) and an increase in recruiting expenses (\$242,000) as well as increased professional expenses and customary costs associated with being a publicly-traded company (\$474,000).

As a result of the increase in research and development expenses, net, as well as the increase in general and administrative expense the Company's operating loss was \$9.4 million for the nine months ended September 30, 2015, compared to \$3.1 million in the same period in 2014.

Net finance income was \$1.4 million in the nine months ended September 30, 2015 compared to net finance income of \$564,000 in the same period in 2014. The Company's finance income or expenses reflects changes in the fair value of certain warrants issued to private placement investors. These warrants are classified as a financial liability carried at fair value in the income statement. The change in fair value of these warrants during the nine months ended September 30, 2015 resulted in finance income of \$1.6 million.

Net loss for the nine months ended September 30, 2015 was \$8.1 million compared to \$2.5 million in the same period in 2014.

Non-GAAP net loss for the nine months ended September 30, 2015 was \$6.3 million compared to \$3.0 million in the same period in 2014. Reconciliations between GAAP measures and Non-GAAP measures are provided later in this press release.

As of September 30, 2015, cash and cash equivalents, including short-term investments, were \$16.5 million.

Use of Non-GAAP Financial Results

In addition to disclosing financial results calculated in accordance with International Financial Reporting Standards as issued by International Accounting Standards Board (GAAP), the Company's earnings release contains Non-GAAP financial measures of comprehensive loss for the period that exclude the effects of share-based compensation, changes in royalties and other financial liabilities, and Non-GAAP financial measures of shareholders' equity for the period end that excludes the effect of other financial liabilities. 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.

Annual General Meeting of Shareholders - December 1, 2015

Check Cap will hold its Annual General Meeting of Shareholders on December 1, 2015 to approve the following items:

- (1) To elect five directors to serve as members of the Company's Board of Directors (to serve in addition to the two external directors under Israeli law) until the Company's next Annual General Meeting of Shareholders;
- (2) To approve the compensation to be paid to each of the non-employee directors (other than the Chairman of the Board and the external directors under Israeli law), subject to their election at the meeting;
- (3) To ratify and approve the reappointment of Brightman AlmagorZohar & Co., a member of Deloitte Touche Tohmatsu, as the Company's independent auditor for the year ending December 31, 2015 and for such additional period until its next annual general meeting;
- (4) To approve the payment of an annual cash bonus to Mr. Guy Neev, the Company's former Chief Executive Officer;
- (5) To approve bonus objectives and payout terms for the period ending December 31, 2015 for the Chief Executive Officer;
- (6) To approve bonus objectives and payout terms for the period ending December 31, 2015 for the Chief Technology Officer;
- (7) To amend Articles 45(a) of the Company's articles of association regarding the appointment of alternate directors; and
- (8) To review and discuss the Company's financial statements for the year ended December 31, 2014.

Proxy materials will be mailed to shareholders of record as of October 26, 2015, and will also be available in the Investor Relations section of the Company's website.

About Check-Cap

Check-Cap is a clinical stage medical diagnostics company developing the first non-invasive system for preparation-free imaging of the colon to identify precancerous polyps and cancers. The Company is developing an ingestible capsule that utilizes proprietary, ultra-low-energy X-ray-based technology to safely generate high-resolution, 3-dimensional imagery of the interior of the colon. Without requiring traditional bowel cleansing 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.

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Financial Tables to Follow

CHECK-CAP LTD. CONSOLIDATED STATEMENTS OF FINANCIAL POSITION (U.S. dollars in thousands)

	<u>September 30,</u> <u>2015</u> <u>(Unaudited)</u>	<u>December 31,</u> <u>2014</u> <u>(Audited)</u>
Assets		
Current assets		
Cash and cash equivalents	9,743	1,075
Restricted deposit	46	46
Short term investments	6,800	
Receivables on account of share options	-	4,800
Other current assets	334	117

Total current assets	<u>16,923</u>	<u>6,038</u>
Non-current assets		
Property and equipment, net	335	191
Deferred issuance costs	<u>-</u>	<u>1,556</u>
Total non-current assets	<u>335</u>	<u>1,747</u>
Total assets	<u>17,258</u>	<u>7,785</u>
Liabilities and shareholders' equity		
Current liabilities		
Trade accounts payable	394	333
Other current liabilities	232	1,369
Employee benefits	<u>980</u>	<u>1,122</u>
Total current liabilities	<u>1,606</u>	<u>2,824</u>
Non-current liabilities		
Royalties provision	2,879	2,509
Other financial liabilities	<u>3,272</u>	<u>225</u>
Total non-current liabilities	<u>6,151</u>	<u>2,734</u>
Shareholders' equity		
Preferred share capital	-	226
Ordinary share capital	546	53
Premium on preferred shares	-	21,167
Share options	-	6,593
Premium on ordinary shares	40,100	6
Capital reserve for ordinary share-based payment	3,508	743
Accumulated deficit	<u>(34,653)</u>	<u>(26,561)</u>
Total shareholders' equity	<u>9,501</u>	<u>2,227</u>
Total liabilities and shareholders' equity	<u>17,258</u>	<u>7,785</u>

CHECK-CAP LTD.
CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME
(U.S. dollars in thousands, except per share data)

	Nine months ended September 30,		Three months ended September 30,	
	2015	2014	2015	2014
	(Unaudited)			
Research and development expenses, net	4,336	2,220	1,603	580
General and administrative expenses	<u>5,109</u>	<u>865</u>	<u>1,409</u>	<u>301</u>
Operating loss	<u>9,445</u>	<u>3,085</u>	<u>3,012</u>	<u>881</u>
Finance income	(1,766)	(568)	(3,172)	(508)
Finance expenses	<u>413</u>	<u>4</u>	<u>208</u>	<u>(81)</u>
Finance income, net	<u>(1,353)</u>	<u>(564)</u>	<u>(2,964)</u>	<u>(589)</u>
Loss for the period	<u>8,092</u>	<u>2,521</u>	<u>48</u>	<u>292</u>
Total comprehensive loss for the period	<u>8,092</u>	<u>2,521</u>	<u>48</u>	<u>292</u>
Loss per ordinary share (in USD) Basic and diluted	<u>0.71</u>	<u>1.55</u>	<u>0.01</u>	<u>0.18</u>
Weighted average number of ordinary shares outstanding - basic and diluted (in thousands)	<u>11,438</u>	<u>1,627</u>	<u>13,276</u>	<u>1,627</u>

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

	Nine months ended September 30,		Three months ended September 30	
	2015	2014	2015	2014
	(Unaudited)			
GAAP total comprehensive loss for the period	8,092	2,521	48	292
Share-based compensation (1)	(3,169)	(51)	(480)	(11)
Current changes in provision for royalties and other financial liabilities	1,394	532	3,044	560
Non-GAAP total comprehensive loss for the period	6,317	3,002	2,612	841
(1) Share based compensation:				
Research and development expenses, net	679	43	108	10
General and administrative expenses	2,490	8	372	1
	3,169	51	480	11

	September 30,
	2015
	(Unaudited)
GAAP total shareholders' equity	9,501
Other financial liabilities	3,272
Non-GAAP total shareholders' equity	12,773

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<https://ir.check-cap.com/2015-10-22-Check-Cap-Reports-Third-Quarter-2015-Financial-Results>