



Check-Cap Reports Second Quarter 2018 Financial Results

ISFIYA, Israel, July 31, 2018 /PRNewswire/ -- Check-Cap Ltd. (the "Company" or "Check-Cap") (NASDAQ: CHEK) (NASDAQ: CHEKW) (NASDAQ: CHEKZ), a clinical stage medical diagnostics company engaged in the development of C-Scan®, an ingestible capsule-based device for preparation-free colorectal cancer screening, today announce financial results for the second quarter and six months ended June 30, 2018.

Recent Highlights

- Continued progress on post CE approval study using C-Scan device version 3 that incorporates the latest algorithms and system optimization. Interim results expected by end of the third quarter 2018.
- Applied to register the C-Scan Version 3 device for marketing and sale in Israel.
- Progress on manufacturing collaboration with GE Healthcare ("GE") towards U.S. pilot study initiation. Manufacturing line and U.S. pilot study initiation remain on target in the fourth quarter 2018.
- Presentation by Dr. Elizabeth E. Half, MD, Head of GI Cancer Prevention Unit and Familial Cancer Syndrome Clinic Gastroenterology Institute at the RAMBAM Healthcare Campus on a comparative study titled "Prepless CRC Screening is Feasible with a Novel X-ray Imaging Capsule," at Digestive Disease Week ongoing Advance in Colorectal Polyp Detection Session, Washington DC. Dr. Half's presentation highlighted that study data from 45 analyzed patients showed C-Scan and FIT sensitivity (ability to correctly identify polyps) of 44% and 37%, respectively, with C-Scan sensitivity increasing to 78% when >50% of the colon surface area was imaged and a linear correlation was observed between imaged area and sensitivity. In addition, C-Scan safety in the study was demonstrated, with no reported adverse events, low radiation (average radiation dose of 0.05ms), and transit time of 52 ± 32 hrs. Further, in an updated scanning algorithm, retrospectively implemented on the study data and recently featured in a May 2018 article in Gut - an official peer-reviewed journal of the British Society of Gastroenterology, a significant increase in number of subjects with imaged area >50% was shown, from 21/45 to 41/45 (from 46% to 91%), following the new algorithm implementation. C-Scan specificity (ability to correctly identify lack of polyps) in those cases approached 90%.
- Regained compliance with Nasdaq minimum bid price requirement. The Company announced and began to trade on the NASDAQ Capital Market on a post 1-for-12 reverse share split adjusted basis in April 2018.
- Closed a \$20.2 million underwritten public offering (including the exercise in full of the underwriter's option to purchase additional securities) of 3,189,381 units with each unit consisting of one ordinary share (or ordinary share equivalent) and one Series C warrant to purchase one ordinary share, along with the exercise in full by the underwriter of its option to purchase an additional 478,407 ordinary shares and Series C warrants to purchase up to 478,407 ordinary shares ("Offering").
- Received grant from Israeli Innovation Authority of approximately \$300,000.

Alex Ovadia, CEO of Check-Cap, stated: "We are pleased to report a quarter of ongoing progress in our clinical, regulatory and operational activities in line with our goal to provide a patient-friendly, preparation free colon-cancer screening device. With funds to continue developing our programs through the end of 2019 secured in May 2018, we look forward to delivering on our milestones for the remainder of 2018. This includes interim data readout from our post CE Mark approval study, which is expected in 3Q18. We are also excited as we advance our GE Manufacturing line collaboration and regulatory path in the US towards the expected initiation of our U.S. pilot trial in 4Q18. We look forward to providing timely updates as we execute on our initiatives."

Financial Results for the Second Quarter Ended June 30, 2018

Research and development expenses, net were \$1.7 million in the three months ended June 30, 2018, compared to \$2.0 million in the same period in 2017. The decrease is primarily attributable to \$273,000 decline in salaries and related expenses as a result of reduction in head count.

General and administrative expenses were \$950,000 in the three months ended June 30, 2018, compared to \$810,000 in the same period in 2017. The increase was primarily due to a \$96,000 increase in professional fees, \$98,000 increase in other general and administrative expenses and \$15,000 increase in salaries and related expenses. This was offset primarily by a \$69,000 decrease in share-based compensation.

Operating loss was \$2.7 million for the three months ended June 30, 2018, compared to \$2.8 million in the same period in 2017.

Finance income, net was \$30,000 in the three months ended June 30, 2018, compared to \$20,000 finance expenses in the same period in 2017.

Net loss was \$2.7 million in the three months ended June 30, 2018, compared to \$2.8 million in the same period in 2017.

Non-GAAP net loss was \$2.6 million in the three months ended June 30, 2018, compared to \$2.7 million in the same period in 2017.

Cash, cash equivalents and short-term bank deposit totaled \$20 million at June 30, 2018, compared to \$4.6 million at March 31, 2018. Check-Cap's cash balance as of June 30, 2018 includes the net proceeds from the May 8, 2018 underwritten public offering (the "2018 Public Offering").

Financial Results for the Six Months Ended June 30, 2018

Research and development expenses, net were \$3.4 million in the six months ended June 30, 2018, compared to \$3.9 million in the same period in 2017. The decrease is primarily attributable to \$529,000 decrease in salaries and related expenses as a result of reduction in head count.

General and administrative expenses were \$1.4 million in the six months ended June 30, 2018, compared to \$1.7 million in the same period in 2017. The decrease was primarily due to a decrease of \$699,000 in share based compensation due to reversal of expenses associated with an equity award of the Company's former CEO which was forfeited as a result of his separation from employment. This was partially offset by a \$230,000 increase in salary and related expenses primarily due to a onetime payment to the Company's former CEO as a result of his separation from employment, a \$98,000 increase in professional expenses and a \$77,000 increase in other general and administrative expenses.

Operating loss was \$4.8 million for the six months ended June 30, 2018, compared to \$5.6 million in the same period in 2017.

Finance income, net was \$9,000 in the six months ended June 30, 2018, compared to \$90,000 in the same period in 2017.

Net loss was \$4.8 million in the six months ended June 30, 2018, compared to \$5.5 million in the same period in 2017.

Non-GAAP net loss was \$5.1 million in the six months ended June 30, 2018, and in the same period in 2017.

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

Net cash used in operating activities was \$4.8 million in the six months ended June 30, 2018, compared to \$5 million in the same period in 2017.

The number of outstanding ordinary shares as of June 30, 2018, was 5,291,357. This number includes the 3,667,788 ordinary shares that were issued in the May 8, 2018 underwritten public offering.

[Financial Tables to Follow]

About Check-Cap

Check-Cap is a clinical-stage medical diagnostics company developing C-Scan®, an ingestible capsule-based device for preparation-free colorectal cancer screening.

Utilizing innovative ultra-low dose X-ray and wireless communication technologies, the capsule generates information on the contours of the inside of the colon as it passes naturally. This information is used to create a 3D map of the colon, which allows physicians to look for polyps and other abnormalities. Designed to improve the patient experience and increase the willingness of individuals to participate in recommended colorectal cancer screening, C-Scan removes many frequently-cited barriers, such as laxative bowel preparation, invasiveness and sedation.

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 and changes in royalties provision. 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 ongoing 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.

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 "Forward-looking Statements" and "Risk Factors" in the Company's Annual Report on Form 20-F for its fiscal year ended December 31, 2017 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.

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

	<u>June 30,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
Assets		
Current assets		
Cash and cash equivalents	9,957	6,997
Short-term bank deposit	10,017	-
Prepaid expenses and other current assets	371	406
Total current assets	<u>20,345</u>	<u>7,403</u>
Non-current assets		
Property and equipment, net	436	503
Total non-current assets	<u>436</u>	<u>503</u>
Total assets	<u>20,781</u>	<u>7,906</u>
<u>Liabilities and shareholders' equity</u>		
Current liabilities		
Accounts payable and accruals		
Trade	531	608
Other	370	347
Other current liabilities	4	5
Employees and payroll accruals	890	602
Total current liabilities	<u>1,795</u>	<u>1,562</u>
Non-current liabilities		
Royalties provision	464	439
Total non-current liabilities	<u>464</u>	<u>439</u>
<u>Shareholders' equity</u>		
Share capital	3,429	974
Additional paid-in capital	72,587	57,643
Accumulated deficit	(57,494)	(52,712)
Total shareholders' equity	<u>18,522</u>	<u>5,905</u>
Total liabilities and shareholders' equity	<u>20,781</u>	<u>7,906</u>

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,	
	2018	2017	2018	2017
Research and development expenses, net	3,357	3,874	1,737	1,997
General and administrative expenses	1,435	1,696	950	810
Operating loss	4,792	5,570	2,687	2,807
Finance income (expenses), net	9	90	30	(20)
Loss before tax	4,783	5,480	2,657	2,827
Tax expenses (gains) on income	(1)	6	(2)	3
Net loss for the period	4,782	5,486	2,655	2,830
Net loss per ordinary share basic and diluted	1.74	3.96	0.70	2.02
Weighted average number of ordinary shares outstanding - basic and diluted (in thousands)	2,741	1,386	3,796	1,403

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

	Six months ended June 30,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss for the period	(4,782)	(5,486)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	82	73
Share-based compensation	(393)	347
Financial income (expense), net	27	(158)
Changes in assets and liabilities items:		
Decrease (increase) in prepaid and other current assets	35	(182)
Increase (decrease) in trade accounts payable, accruals and other current liabilities	(131)	107
Increase in employees and payroll accruals	288	223
Increase in royalties provision	25	49
Net cash used in operating activities	(4,849)	(5,027)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(8)	(81)
Proceeds from short-term investments	(10,000)	-

Net cash (used in) investing activities	<u>(10,008)</u>	<u>(81)</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Exercise of pre funded warrants into ordinary shares	4	82
Issuance of ordinary shares in the June 2017 RD Offering, net of issuance expenses in an amount of \$349	-	2,380
Issuance of ordinary shares in the 2018 Public Offering, net of issuance expenses in an amount of \$2,381	<u>17,858</u>	<u>-</u>
Net cash provided by financing activities	<u>17,862</u>	<u>2,462</u>
Effect of exchange rate changes on cash and cash equivalents	(45)	159
Net Increase (decrease) in cash and cash equivalents	2,960	(2,487)
Cash and cash equivalents at the beginning of the period	<u>6,997</u>	<u>11,639</u>
Cash and cash equivalents at the end of the period	<u>9,957</u>	<u>9,152</u>

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,	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
GAAP net loss for the period	(4,782)	(5,486)	(2,655)	(2,830)
Share-based compensation (1)	(393)	347	43	133
Changes in royalties	<u>25</u>	<u>49</u>	<u>7</u>	<u>25</u>
Non-GAAP net loss for the period	<u>(5,150)</u>	<u>(5,090)</u>	<u>(2,605)</u>	<u>(2,672)</u>
(1) Share-based compensation:				
Research and development expenses, net	34	75	10	31
General and administrative expenses:				
General and administrative expenses	75	272	33	102
One time reversal of equity award to the Company's Former CEO	<u>(502)</u>	<u>-</u>	<u>-</u>	<u>-</u>
	<u>(393)</u>	<u>347</u>	<u>43</u>	<u>133</u>

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