



Check-Cap Reports First Quarter 2019 Financial Results

Initiates U.S. pilot study of C-Scan® at NYU School of Medicine and Mayo Clinic

ISFIYA, Israel, May 13, 2019 /PRNewswire/ -- [Check-Cap Ltd.](#) (the "Company" or "Check-Cap") (NASDAQ: CHEK) (NASDAQ: CHEKW), (NASDAQ: CHEKZ), a clinical stage medical diagnostics company advancing the development of C-Scan®, the first and only preparation-free ingestible capsule for the prevention of colorectal cancer through the detection of precancerous polyps, today announced financial results for the first quarter ended March 31, 2019.

Recent Highlights:

- Announced the initiation of the U.S. pilot study of C-Scan®, and also announced that the first patients have ingested the capsule at the NYU School of Medicine
- Announced that Mayo Clinic is the second trial site participating in the ongoing U.S. pilot study of C-Scan®
- Appointed Ms. Mira Rosenzweig to the position of Chief Financial Officer, bringing nearly 20 years of executive financial management experience to the Check-Cap team
- Received an extension from the Israeli Ministry of Health, Medical Device Division (known as AMAR) to commence commercial sales of C-Scan® in Israel, valid until March 31, 2020
- Completed a registered direct offering that raised gross proceeds of \$7.5 million that provides additional funding to advance clinical development of C-Scan® in the U.S.

"During the first quarter, we achieved a significant milestone for our Company with the initiation of our U.S. pilot study of C-Scan® and subsequent successful ingestions of the capsule by patients at NYU School of Medicine and Mayo Clinic, two world-renowned healthcare institutions," said Alex Ovadia, chief executive officer of Check-Cap. "As we seek to advance development of C-Scan® in the U.S., we look forward to data from this important study to enable the design of our U.S. pivotal trial, which we expect to initiate during 2020. Obtaining regulatory approval in the U.S. remains our highest corporate priority."

"We believe the availability of a patient-friendly, preparation-free colon cancer screening alternative such as C-Scan® can fundamentally alter the screening and prevention paradigm and significantly increase screening rates globally, leading to improved outcomes for patients while creating long-term value for our shareholders," Mr. Ovadia concluded.

Financial Results for the First Quarter Ended March 31, 2019

Research and development expenses net, were \$2.3 million for the three months ended March 31, 2019, compared to \$1.6 million for the same period in 2018. The increase was primarily due to the Company's ongoing post-CE Mark clinical study and expanded preparations for the U.S. pilot study. This increase was partially offset by a \$58,000 grant received from the Israel Innovation Authority.

General and administrative expenses were \$825,000 for the three months ended March 31, 2019, compared to \$485,000 for the same period in 2018. The increase was primarily due to a \$408,000 increase in share based compensation expense. In addition, professional services fees were \$92,000 higher in the three months ended March 31, 2019, compared to the three months ended March 31, 2018. This increase was partially offset by a \$245,000 decrease in salaries and related expenses.

Operating loss was \$3.2 million for the three months ended March 31, 2019, compared to an operating loss of \$2.1 million for the same period in 2018.

Financial income, net was \$14,000 for the three months ended March 31, 2019, compared to \$21,000 of financial expenses, net for the same period in 2018.

Net loss was \$3.2 million for the three months ended March 31, 2019, compared to \$2.1 million for the same period in 2018.

Cash and cash equivalents, restricted cash and short-term bank deposits totaled \$17.3 million as of March 31, 2019, compared with \$14.6 million as of December 31, 2018.

Net cash used in operating activities was \$3.8 million for the three months ended March 31, 2019, compared to \$2.3 million for the same period in 2018.

In February 2019, we completed a registered direct offering for net proceeds of \$6.5 million.

[Financial Tables to Follow]

About Check-Cap

Check-Cap is advancing the development of C-Scan®, the first and only preparation-free ingestible scanning capsule for the prevention of colorectal cancer (CRC) through the detection of precancerous polyps. The patient-friendly test has the potential to increase screening adherence and reduce the overall incidence of CRC. The C-Scan® system utilizes an ultra-low dose X-ray capsule, an integrated positioning, control, and recording system, as well as proprietary software to generate a 3D map of the inner lining of the colon. C-Scan® is non-invasive and requires no preparation or sedation, allowing the patient to continue their daily routine with no interruption as the capsule is propelled through the gastrointestinal tract by natural motility.

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 "Forward-looking Statements" and "Risk Factors" in the Company's Annual Report on Form 20-F for the year ended December 31, 2018 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>March 31,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
Assets		
Current assets		
Cash and cash equivalents	7,974	8,572
Restricted cash	350	350
Short-term bank deposit	9,000	5,643
Prepaid expenses and other current assets	535	419
Total current assets	<u>17,859</u>	<u>14,984</u>
Non-current assets		
Property and equipment, net	432	452
Total non-current assets	<u>432</u>	<u>452</u>
Total assets	<u>18,291</u>	<u>15,436</u>
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable and accruals		
Trade	645	1,113
Other	318	214
Other current liabilities	12	35
Employees and payroll accruals	619	859
Total current liabilities	<u>1,594</u>	<u>2,221</u>
Non-current liabilities		

Royalties provision	<u>206</u>	<u>185</u>
Total non-current liabilities	<u>206</u>	<u>185</u>
Shareholders' equity		
Share capital	5,384	3,456
Additional paid-in capital	77,554	72,888
Accumulated other comprehensive loss	4	(13)
Accumulated deficit	<u>(66,451)</u>	<u>(63,301)</u>
Total shareholders' equity	<u>16,491</u>	<u>13,030</u>
Total liabilities and shareholders' equity	<u>18,291</u>	<u>15,436</u>

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

	Three months ended March 31,	
	2019	2018
Research and development expenses, net	2,339	1,620
General and administrative expenses	825	485
Operating loss	<u>3,164</u>	<u>2,105</u>
Financial income (expenses), net	14	(21)
Loss before tax	3,150	2,126
Taxes on income	-	1
Net loss	<u>3,150</u>	<u>2,127</u>
Comprehensive loss:		
Net loss	3,150	2,127
Change in fair value of cash flow hedge	(4)	-
Comprehensive loss	<u>3,146</u>	<u>2,127</u>
Net loss per ordinary share (in USD) basic and diluted	<u>0.44</u>	<u>1.27</u>
Weighted average number of ordinary shares outstanding - basic and diluted (in thousands)	<u>7,114</u>	<u>1,674</u>

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

	Three months ended March 31,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss for the period	(3,150)	(2,127)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	28	43

Share-based compensation	83	(436)
Financial expense (income), net	(27)	14
Changes in assets and liabilities items:		
Decrease (increase) in prepaid and other current assets and non-current assets	(116)	8
Decrease in trade accounts payable, accruals and other current liabilities	(375)	(19)
Increase (decrease) in employees and payroll accruals	(240)	161
Increase in royalties provision	21	18
Net cash used in operating activities	<u>(3,776)</u>	<u>(2,338)</u>
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(3)	(1)
Investment in short-term investments/bank deposit	(3,357)	-
Net cash provided by (used in) investing activities	<u>(3,360)</u>	<u>(1)</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Issuance of ordinary shares in the 2019 registered direct Offering	6,511	-
Net cash provided by financing activities	<u>6,511</u>	<u>-</u>
Effect of exchange rate changes on cash, cash equivalents and restricted cash	27	(14)
Net decrease in cash, cash equivalents and restricted cash	(598)	(2,353)
Cash, cash equivalents and restricted cash at the beginning of the period	8,922	6,997
Cash, cash equivalents and restricted cash at the end of the period	<u>8,324</u>	<u>4,644</u>

Investor Contacts

Jeremy Feffer
LifeSci Advisors, LLC
212-915-2568
jeremy@lifesciadvisors.com

Meirav Gomeh-Bauer
LifeSci Advisors, LLC
+972(0)-54-476-4979
Meirav@lifesciadvisors.com

SOURCE Check-Cap Ltd.

<https://ir.check-cap.com/2019-05-13-Check-Cap-Reports-First-Quarter-2019-Financial-Results>