



Check-Cap Reports Fourth Quarter and Full-Year 2018 Financial Results

ISFIYA, Israel, March 28, 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 capsule based screening method for the prevention of colorectal cancer through the detection of precancerous polyps, today announced financial results for the fourth quarter and full-year ended December 31, 2018.

Recent Highlights:

- Announced appointment of Mira Rosenzweig as Chief Financial Officer, bringing nearly 20 years of executive financial management experience to the Check-Cap team.
- Announced approval by the New York University School of Medicine Institutional Review Board (IRB) of a single-arm U.S. pilot study of the C-Scan® system to evaluate its safety, usability, and subject compliance.
- Continued to move forward with the Company's collaboration with its manufacturing partner, GE Healthcare.
- Completed a registered direct offering that raised gross proceeds of \$7.5 million, which provides additional funding to advance the clinical development of the C-Scan® system in the U.S. while preparing for commercialization in Israel and the E.U.

Alex Ovadia, chief executive officer of Check-Cap, stated, "During 2018, we made significant progress on a number of fronts, as we are working to develop clear paths to commercialization in major markets worldwide."

"In parallel, we continued to advance regulatory and development activities in the United States, including a single-arm U.S. pilot study. We look forward to data from this important study as we work to advance the C-Scan® system toward commercialization in the U.S., which remains our highest corporate priority."

"The C-Scan® system has the potential to increase screening rates by offering patients a non-invasive, preparation-free alternative to colonoscopy for the detection of precancerous polyps, and we are excited about the potential of this technology to improve patient outcomes globally," Mr. Ovadia concluded.

Financial Results for the Fourth Quarter Ended December 31, 2018

Research and development expenses, net were \$2.4 million for the three months ended December 31, 2018, compared to \$1.4 million for the same period in 2017. The increase is primarily attributable to a \$266,000 increase in salaries and related expenses, a \$185,000 increase in share-based compensation, a \$476,000 increase in materials and a \$152,000 increase in other research and development expenses. The increase in materials and other research and development expenses relate to the Company's clinical trials, primarily its post-CE Mark study and ongoing preparations for its U.S. pilot study. The increase was partially offset by a \$57,000 grant received from the Israel Innovation Authority.

General and administrative expenses were \$1.1 million for the three months ended December 31, 2018, compared to \$658,000 for the same period in 2017. The increase was primarily due to a \$219,000 increase in professional fees, a \$176,000 increase in other general and administrative expenses, both as a result of being a public company, and a \$68,000 increase in salaries and related expenses. The increase was partially offset by a \$48,000 decrease in share-based compensation.

Cash and cash equivalents, restricted cash and short-term bank deposits totaled \$14.6 million at December 31, 2018, compared to \$17.6 million at September 30, 2018 and \$7 million at December 31, 2017.

Operating loss was \$3.5 million for the three months ended December 31, 2018, compared to \$2.1 million for the same period in 2017.

Finance income, net was \$365,000 for the three months ended December 31, 2018, compared to \$156,000 for the same period in 2017, as a result of higher income from a change in royalties' provision and higher interest income on short term deposits.

Net loss was \$3.1 million for the three months ended December 31, 2018, compared to \$1.9 million for the same period in 2017.

Financial Results for the Twelve Months Ended December 31, 2018

Research and development expenses net, were \$7.62 million for the year ended December 31, 2018, compared to

\$6.84 million for the same period in 2017. The increase is primarily due to a \$894,000 increase in materials and a \$206,000 increase in other research and development expenses, both relating to the Company's clinical trials, primarily in connection with the Company's post-CE Mark clinical study and the preparation for the U.S. pilot study including obtaining FDA approval. The increase in research and development expenses, was partially offset by a \$246,000 decrease in salaries and related expenses, primarily due to the shift of Mr. Ovadia from research and development to general and administrative as the company CEO.

General and administrative expenses were \$3.45 million for the year ended December 31, 2018, compared to \$3.16 million for the same period in 2017. The increase was primarily due to a \$444,000 increase in salaries and related expenses, primarily due to a \$281,000 in severance paid to the Company's former CEO, a \$419,000 increase in professional fees primarily due to a \$202,000 increase in legal fees, and a \$325,000 increase in other general and administrative expenses, primarily associated with consulting fees and services incurred as a result of being a public company. The increase was partially offset by a \$909,000 decrease in share-based compensation, which \$502,000 relates to reversal of expenses associated with an equity award to our former CEO which was forfeited as a result of his separation from employment.

Operating loss was \$11.1 million for the year ended December 31, 2018, compared to \$10.0 million for the same period in 2017.

Finance income, net was \$473,000 for the year ended December 31, 2018, compared to \$236,000 for the same period in 2017, as a result of higher income from a change in royalties' provision and higher interest income on short term deposits.

Net loss was \$10.6 million for the year ended December 31, 2018, compared to \$9.8 million for the same period in 2017.

A copy of the Company's annual report on Form 20-F for the year ended December 31, 2018 has been filed with the U.S. Securities and Exchange Commission at www.sec.gov and posted on the Company's investor relations website at <http://ir.check-cap.com/>. The Company will deliver a hard copy of its annual report, including its complete audited consolidated financial statements, free of charge, to its shareholders upon request to Rachel.Cohen-Menirom@check-cap.com.

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.

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 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.

	Note	December 31,	
		2018	2017
Assets			
Current assets			
Cash and cash equivalents		8,572	6,997
Restricted cash		350	-
Short-term bank deposit		5,643	-
Prepaid expenses and other current assets		419	406
Total current assets		14,984	7,403
Non-current assets			
Property and equipment, net		452	503
Total non-current assets		452	503
Total assets		15,436	7,906
Liabilities and shareholders' equity			
Current liabilities			
Accounts payable and accruals			
Trade		1,113	608
Other		214	347
Other current liabilities		35	5
Employees and payroll accruals		859	602
Total current liabilities		2,221	1,562
Non-current liabilities			
Royalties provision		185	439
Total non-current liabilities		185	439
Shareholders' equity			
Share capital		3,456	974
Additional paid-in capital		72,888	57,643
Other comprehensive loss		(13)	-
Accumulated deficit		(63,301)	(52,712)
Total shareholders' equity		13,030	5,905
Total liabilities and shareholders' equity		15,436	7,906

The accompanying notes to the consolidated financial statements are an integral part of them.

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

	Year ended December 31,		Three months ended December 31,	
	2018	2017	2018	2017
Research and development expenses, net	7,618	6,837	2,396	1,400
	3,445	3,164	1,073	658
General and administrative expenses				
Operating loss	11,063	10,001	3,469	2,058
Finance income, net	473	236	365	156
Loss before tax	10,590	9,765	3,104	1,902
Tax expenses (gains) on income	(1)	6	-	-
Net loss for the period	10,589	9,771	3,104	1,902
Comprehensive loss:				
Net loss	10,589	9,771	3,104	1,902
Change in fair value of cash flow hedge	13	-	(28)	-

Comprehensive loss	<u>10,602</u>	<u>9,771</u>	<u>3,076</u>	<u>1,902</u>
Loss per share:				
Net loss per ordinary share basic and diluted	2.61	6.72	0.58	1.22
Weighted average number of ordinary shares outstanding - basic and diluted (in thousands)	4,058	1,455	5,352	1,562

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

	Year ended December 31,		Three months ended December 31,	
	2018	2017	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES				
Net loss for the period	(10,589)	(9,771)	(3,104)	(1,902)
Adjustments required to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	147	157	29	42
Share-based compensation	(65)	726	206	69
Financial expenses (income), net	67	(165)	110	(10)
Changes in assets and liabilities items:				
Decrease (increase) in prepaid and other current assets and non-current assets	(13)	(164)	77	(91)
Increase in trade accounts payable, accruals and other current liabilities	416	275	356	211
Increase (decrease) in employees and payroll accruals	258	(126)	(92)	(288)
Decrease in royalties provision	(255)	(82)	(294)	(160)
Net cash used in operating activities	<u>(10,034)</u>	<u>(9,150)</u>	<u>(2,712)</u>	<u>(2,129)</u>
CASH FLOWS FROM INVESTING ACTIVITIES				
Purchase of property and equipment	(94)	(231)	(80)	(10)
Proceeds from short-term bank deposit	(5,629)	-	3,371	-
Net cash provided by (used in) investing activities	<u>(5,723)</u>	<u>(231)</u>	<u>3,291</u>	<u>(10)</u>
CASH FLOWS FROM FINANCING ACTIVITIES				
Exercise of warrants into ordinary shares	-	196	(4)	114
Issuance of ordinary shares in the RD offering, net of issuance expenses	(30)	4,379	(30)	2,071
Issuance of ordinary shares in the 2018 Public Offering	17,792	-	(66)	-
Net cash provided by financing activities	<u>17,762</u>	<u>4,575</u>	<u>(100)</u>	<u>2,185</u>
Effect of exchange rate changes on cash and cash equivalents	(80)	164	(42)	11
Net increase (decrease) in cash and cash equivalents	1,925	(4,642)	437	55
Cash and cash equivalents at the beginning of the period	<u>6,997</u>	<u>11,639</u>	<u>8,485</u>	<u>6,940</u>
Cash and cash equivalents at the end of the period	<u>8,922</u>	<u>6,997</u>	<u>8,922</u>	<u>6,995</u>

Supplemental disclosure of non-cash flow information:

Cashless exercise of warrants to purchase ordinary shares into ordinary shares

33

8

24

Purchase of property and equipment

3

15

35

10

Issuance expenses in the registered direct offering

-

30

-

30

Supplemental disclosure of cash flow information

Cash paid for income taxes

5

3

-

Investor Contacts

Jeremy Feffer

LifeSci Advisors, LLC

+1-212-915-2568

jeremy@lifesciadvisors.com

Meirav Gomeh-Bauer

LifeSci Advisors, LLC

+972(0)-54-476-4979

Meirav@lifesciadvisors.com

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<https://ir.check-cap.com/2019-03-28-Check-Cap-Reports-Fourth-Quarter-and-Full-Year-2018-Financial-Results>