



Check-Cap Reports First Quarter 2022 Financial Results and Corporate Update

Company initiated first part of its U.S. pivotal study in early May 2022

ISFIYA, Israel, June 1, 2022 /PRNewswire/ -- [Check-Cap Ltd.](#) (the "Company" or "Check-Cap") (NASDAQ: CHEK), (NASDAQ: CHEKZ), a clinical stage medical diagnostics company advancing the development of C-Scan®, the first and only patient-friendly, preparation-free screening test to detect polyps before they may transform into colorectal cancer (CRC), today announced financial results for the first quarter ended March 31, 2022.

Q1 2022 and Recent Highlights:

- Earlier in May, after successfully obtaining Institutional Review Board approval, the Company announced the initiation of the first part of its U.S. pivotal study of C-Scan that focuses on device calibration and enhancement of C-Scan algorithms among the average risk U.S. population at Mayo Clinic in Rochester, Minnesota. Elizabeth Rajan, M.D., gastroenterologist, and professor of medicine at Mayo Clinic, is the principal investigator of the study at this site. The Pivotal Study is expected to enroll approximately 1,000 subjects ages 50-75 and will be conducted at up to 15 clinical sites in the U.S. The first part of the trial will enroll up to 200 subjects. The Company is working to enroll new additional study sites in the U.S. and plans to provide updates in the future. The second portion of the trial, anticipated to begin in Q4 2022, will enroll approximately 800 subjects and will compare performance of C-Scan to traditional colonoscopy. Data from this second comparative portion of the study will be analyzed for statistical significance and are intended to serve as the basis for the Company's filing for FDA approval in the U.S.
- In March 2022, the Company consummated a \$10 million registered direct offering. The Company believes that it has sufficient capital to fund its ongoing operations and plans into the first quarter of 2024.

"The initiation of the U.S. pivotal study in May 2022 represents a key milestone in our path to demonstrate the clinical potential of C-Scan and gather final data to support regulatory approval in the U.S.," said Alex Ovadia, chief executive officer of Check-Cap. "We are progressing towards agreements with additional reputable gastroenterology centers in the U.S. to expand patient enrollment across different U.S. geographies. We believe that C-Scan system has the potential to address a significant unmet need, through the introduction of potentially the first patient-friendly and preparation-free screening test to detect polyps before they may transform into cancer, and look forward to advancing to the final clinical stages of research."

Financial Results for the First Quarter Ended March 31, 2022

Net research and development expenses were \$4.1 million for the three months ended March 31, 2022 compared to \$2.4 million for the same period in 2021. The increase is primarily due to (i) an increase of approximately \$0.7 million in salary and related expenses, mainly as a result of increased employee head count, (ii) an increase of approximately \$0.4 million in other research and development expenses, including clinical related expenses, (iii) \$0.2 million increase in material, subcontractors and consultants' expenses, and (iv) an increase of approximately \$0.1 million in share-based compensation. The Company expects that clinical related expenses will increase in the upcoming quarters as it progresses in its ongoing U.S. pivotal study.

The increase in net research and development expenses between 2022 and 2021 is also due to a \$0.3 million grant from the Israel Innovation Authority, which amount was recorded as a deduction from research and development expenses in the three months ended March 31, 2021.

General and administrative expenses were \$1.8 million for the three months ended March 31, 2022, compared to \$1.2 million for the same period in 2021. The increase is primarily due to a \$0.4 million increase in professional services, a \$0.1 million increase in other general expenses, mainly associated with directors' and officers' liability insurance, and a \$0.1 million increase in share-based compensation.

Operating loss was \$5.9 million for the three months ended March 31, 2022, compared to an operating loss of \$3 million for the same period in 2021.

Net finance income was \$51,000 for the three months ended March 31, 2022, compared to net finance expenses of \$9,000 for the same period in 2021.

Net loss was \$5.8 million for the three months ended March 31, 2022, compared to \$3.6 million for the same period in 2021.

Cash and cash equivalents, restricted cash and short-term bank deposits as of March 31, 2022 were \$55.7 million as compared to \$51.9 million as of December 31, 2021. On March 3, 2022, the Company consummated a registered direct offering for the sale of 20,000,000 of the Company's ordinary shares and accompanying warrant to purchase up to an aggregate of 15,000,000 of the Company's ordinary shares. The registered direct offering resulted in gross proceeds to the Company of \$10.0 million or approximately \$8.9 million net of offering expense. The Company believes that it has sufficient capital to fund its ongoing operations and plans into the first quarter 2024.

The number of outstanding ordinary shares as of March 31, 2022 was 116,411,949. As of May 30, 2022, the number of outstanding ordinary shares was 116,411,949.

About Check-Cap

Check-Cap is a clinical stage medical diagnostics company aiming to redefine colorectal cancer (CRC) screening through the introduction of C-Scan®, the first and only patient-friendly preparation-free screening test to detect polyps before they may transform into colorectal cancer and enable early intervention and cancer prevention. The Company's disruptive capsule-based screening technology aims to help millions of people to stay healthy through preventive CRC screening. C-Scan uses 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 as it travels naturally along the gastrointestinal tract. C-Scan is non-invasive and requires no sedation. It requires no bowel preparation, allowing the patients to continue their daily routine with no interruption. C-Scan is not intended to replace colonoscopy. A positive C-Scan result should be followed by colonoscopy. C-Scan is an investigational device and is not available for sale in the United States.

Legal Notice Regarding Forward-Looking Statements

This press release contains "forward-looking statements" about the Company's expectations, beliefs or intentions regarding, among other things, its product development efforts, business, financial condition, results of operations, strategies or prospects. 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, 2021 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.

Investor Contacts

Irina Koffler
LifeSci Advisors, LLC
646.970.4681
ikoffler@lifesciadvisors.com

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

Media Contact

Mónica Rouco Molina
Account Supervisor - Europe
LifeSci Communications
mrroucomolina@lifescicomms.com

	March 31, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	\$ 11,263	\$ 26,457
Restricted cash	350	350
Short-term bank deposit	44,127	25,104
Prepaid expenses and other current assets	860	839
Total current assets	56,600	52,750
Non-current assets		
Property and equipment, net	1,828	1,793
Operating leases	1,162	1,116
Total non-current assets	2,990	2,909
Total assets	\$ 59,590	\$ 55,659
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable and accruals		
Trade	\$ 970	\$ 1,050
Other	1,102	680
Employees and payroll accruals	2,257	1,961
Operating lease liabilities	370	350
Total current liabilities	4,699	4,041
Non-current liabilities		
Royalties provision	134	132
Operating lease liabilities	800	795
Total non-current liabilities	934	927
Shareholders' equity		
Share capital, Ordinary shares, 2.4 NIS par value (360,000,000 authorized shares as of March 31, 2022 and December 31, 2021; 116,411,949 and 96,411,949 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively)	83,602	68,787
Additional paid-in capital	84,374	90,089
Accumulated deficit	(114,019)	(108,185)
Total shareholders' equity	53,957	50,691
Total liabilities and shareholders' equity	\$ 59,590	\$ 55,659

CHECK CAP LTD.

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

	Three months ended March 31,	
	2022	2021
Research and development expenses, net	\$ 4,128	\$ 2,406
General and administrative expenses	1,757	1,151
Operating loss	5,885	3,557
Finance Income (loss), net	51	(9)
Net loss for the period	\$ 5,834	\$ 3,566
Loss per share:		
Net loss per ordinary share basic and diluted	0.06	0.05
Weighted average number of ordinary shares outstanding - basic and diluted	102,634,171	68,071,059

CHECK CAP LTD.**CONSOLIDATED UNAUDITED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY**

(U.S. dollars in thousands, except share and per share data)

	Number of ordinary shares	Amount	Additional paid-in capital	Accumulated deficit	Total shareholders' equity
Balance as of January 1, 2022	96,411,949	\$ 68,787	\$ 90,089	\$ (108,185)	\$ 50,69
Issuance of ordinary shares and warrants in March 2022 registered direct offering, net of issuance expenses in an amount of \$1,150	20,000,000	14,815	(5,965)	-	8,85
Share-based compensation	-	-	250	-	25
Net loss	-	-	-	(5,834)	(5,834)
Balance as of March 31, 2022	116,411,949	\$ 83,602	\$ 84,374	\$ (114,019)	\$ 53,95
	Number of ordinary shares	Amount	Additional paid-in capital	Accumulated deficit	Total shareholders' equity
Balance as of January 1, 2021	46,239,183	\$ 31,646	\$ 75,715	\$ (90,983)	\$ 16,37
Issuance of ordinary shares in private placement, net of issuance expenses in an amount of \$30	24,204,682	18,099	1,120	-	19,21
RSUs vesting	24,395	18	(18)	-	-
Share-based compensation	-	-	73	-	7
Net loss	-	-	-	(3,566)	(3,566)
Balance as of March 31, 2021	70,468,260	\$ 49,763	\$ 76,890	\$ (94,549)	\$ 32,10

CHECK-CAP LTD.**CONSOLIDATED STATEMENTS OF CASH FLOWS**

(U.S. dollars in thousands)

	Three months ended March 31,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (5,834)	\$ (3,566)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	76	43
Share-based compensation	250	73
Financial income, net	(51)	(57)
Changes in assets and liabilities items:		
Increase in prepaid and other current assets and non-current assets	(18)	(142)
Increase in trade accounts payable, accruals and other current liabilities	389	85
Increase in employees and payroll accruals	296	208
Increase in royalties provision	3	42
Net cash used in operating activities	\$ (4,889)	\$ (3,314)

CASH FLOWS FROM INVESTING ACTIVITIES

Purchase of property and equipment	(200)	(33)
Investment in short-term bank and other deposits, net	(18,999)	(8,381)
Net cash used in investing activities	\$ (19,199)	\$ (8,414)

CASH FLOWS FROM FINANCING ACTIVITIES

Exercise of warrants into ordinary shares, net of issuance expenses	-	19,219
Issuance of ordinary shares in the registered direct offerings, net of issuance expenses	8,894	-
Net cash provided by financing activities	\$ 8,894	\$ 19,219
Net (decrease) increase in cash, cash equivalents and restricted cash	(15,194)	7,491
Cash, cash equivalents and restricted cash at the beginning of the period	26,807	8,053
Cash, cash equivalents and restricted cash at the end of the period	\$ 11,613	\$ 15,544


Supplemental disclosure of non-cash flow information:

Purchase of property and equipment included in accounts payable and accrued expenses	\$ 71	\$ 32
Payable due to issuance costs	45	-
Assets acquired under operating leases	129	916

Supplemental disclosure of cash flow information:

Cash paid for taxes	1	-
Interest received	\$ 61	\$ 6

SOURCE Check-Cap Ltd.

Additional assets available online:  [Photos](#) ⁽¹⁾

<https://ir.check-cap.com/2022-06-01-Check-Cap-Reports-First-Quarter-2022-Financial-Results-and-Corporate-Update>