



Check-Cap Reports Second Quarter 2022 Financial Results and Provides a Corporate Update

ISFIYA, Israel, Aug. 31, 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 and provided a corporate update for the second quarter and six months ended June 30, 2022.

Second Quarter and Recent Highlights:

- Initiated the first part of the 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 and New York University (NYU) School of Medicine. In parallel, Check-Cap is also enrolling average risk patients in Israel, to further optimize C-Scan functionality and patient experience. The required lead time to activate new sites as well as to recruit patients in the U.S. has been longer than expected. The Company is continuing to work on activating new sites while at the same time calibrating the C-Scan device and its algorithms. Assuming sites' activation and calibration proceeds as planned, the Company expects the second part of the U.S. pivotal study to start in mid-2023.
- Nominated Aasma Shaukat, M.D., MPH, a Robert M. and Mary H. Glickman Professor of Gastroenterology and Professor of Population Health, Director of Gastroenterology Outcomes Research at NYU Grossman School of Medicine, as Coordinating Principal Investigator (CPI) for the pivotal study. Dr. Aasma brings two decades of experience as a practicing gastroenterologist and clinical researcher with expertise in colon cancer screening long term outcomes and colorectal cancer non-invasive screening. She is a member of the U.S. Multi-society Task Force on Colorectal Cancer (USMSTF) and was first author of the American College of Gastroenterology (ACG) clinical guideline on Colorectal cancer screening in 2021.
- On August 11, 2022, the Company's shareholders approved a reverse share split of the Company's ordinary shares within a range of 1 for 10 to 1 for 20, with the exact ratio and effective date to be determined by further action of the Company's Board of Directors, and to be announced by the company.

"Since initiation of the pivotal trial in May 2022 we have been diligently working to expand patient enrollment and data collection," said Alex Ovadia, chief executive officer of Check-Cap. "The team is focused on achieving our study objectives and we intend to provide updates in the coming months. We are also pleased to welcome Dr. Shaukat as Coordinating Principal Investigator. Her extensive clinical experience and involvement in the colorectal cancer screening field will be extremely valuable as we continue to advance the study."

Financial Results for the Second Quarter Ended June 30, 2022

Research and development expenses were \$3.5 million for the three months ended June 30, 2022, compared to \$2.8 million for the same period in 2021. The increase is primarily due to (i) an increase of approximately \$0.4 million in salary and related expenses, mainly as a result of increased employee head count, and (ii) an increase of approximately \$0.3 million in other research and development expenses, including clinical related expenses and regulatory consultants. The Company expects that clinical related expenses will increase in the upcoming quarters as it progresses in its ongoing U.S. pivotal study.

General and administrative expenses were \$1.3 million for the three months ended June 30, 2022, compared to \$1.1 million for the same period in 2021. The increase is primarily due to 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 \$4.9 million for the three months ended June 30, 2022, compared to \$3.9 million for the same period in 2021.

Net finance income was \$81,000 for the three months ended June 30, 2022, compared to \$5,000 for the same period in 2021.

Net loss was \$4.8 million for the three months ended June 30, 2022, compared to \$3.9 million for the same period in 2021.

Cash and cash equivalents, restricted cash and short-term bank deposits as of June 30, 2022 were \$50.2 million, compared with \$55.7 million as of March 31, 2022 and \$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 warrants 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 expenses. The Company believes that it has sufficient capital to fund its ongoing operations and plans into the second quarter of 2024.

Financial Results for the Six Months Ended June 30, 2022

Research and development expenses were \$7.7 million for the six months ended June 30, 2022, compared to \$5.0 million for the same period in 2021. The increase is primarily due to (i) an increase of approximately \$1.2 million in salary and related expenses, mainly as a result of increased employee head count, (ii) an increase of approximately \$0.8 million in other research and development expenses, including clinical related expenses and regulatory consultants and (iii) an increase of approximately \$0.2 million in share-based compensation. 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 six months ended June 30, 2021.

General and administrative expenses were \$3.1 million for the six months ended June 30, 2022, compared to \$2.0 million for the same period in 2021. The increase is primarily due to a \$0.4 million increase in professional services, a \$0.2 million increase in other general expenses, mainly associated with directors' and officers' liability insurance, and a \$0.2 million increase in share-based compensation.

Operating loss was \$10.8 million for the six months ended June 30, 2022, compared to \$7.5 million for the same period in 2021.

Net finance income was \$132,000 for the six months ended June 30, 2022, compared to finance loss of \$4,000 for the same period in 2021.

Net loss was \$10.6 million for the six months ended June 30, 2022, compared to \$7.5 million for the same period 2021.

Net cash used in operating activities was \$10.3 million for the six months ended June 30, 2022, compared to \$7.8 million for the same period in 2021.

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.

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

	June 30, 2022 Unaudited	December 31, 2021 Audited
<u>Assets</u>		
Current assets		
Cash and cash equivalents	\$ 11,637	\$ 26,457
Restricted cash	351	350
Short-term bank deposit	38,206	25,104
Prepaid expenses and other current assets	996	839
Total current assets	51,190	52,750
Non-current assets		
Property and equipment, net	1,836	1,793
Operating leases	1,100	1,116
Total non-current assets	2,936	2,909
Total assets	\$ 54,126	\$ 55,659
<u>Liabilities and shareholders' equity</u>		
Current liabilities		
Accounts payable and accruals		
Trade	\$ 946	\$ 1,050
Other	701	680
Employees and payroll accruals	1,668	1,961
Other current liabilities	279	-
Operating lease liabilities	332	350
Total current liabilities	3,926	4,041
Non-current liabilities		
Royalties provision	107	132
Operating lease liabilities	669	795
Total non-current liabilities	776	927
<u>Shareholders' equity</u>		
Share capital, Ordinary shares, 2.4 NIS par value (360,000,000 authorized shares as of June 30, 2022 and December 31, 2021, respectively; 116,411,949 and 96,411,949 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively)	83,602	68,787
Additional paid-in capital	84,648	90,089
Accumulated deficit	(118,826)	(108,185)
Total shareholders' equity	49,424	50,691

Total liabilities and shareholders' equity\$ 54,126 \$ 55,659

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

	Six months ended June 30,		Three months ended June 30,	
	2022	2021	2022	2021
Research and development expenses, net	\$ 7,673	\$ 5,187	\$ 3,545	\$ 2,781
General and administrative expenses	3,100	2,293	1,343	1,142
Operating loss	10,773	7,480	4,888	3,923
Finance Income (loss), net	132	(4)	81	5
Loss before income tax	10,641	7,484	4,807	3,918
Net loss for the period	\$ 10,641	\$ 7,484	\$ 4,807	\$ 3,918
Loss per share:				
Net loss per ordinary share basic and diluted	\$ 0.10	\$ 0.11	\$ 0.04	\$ 0.06
Weighted average number of ordinary shares outstanding - basic and diluted	109,561,120	69,284,917	116,411,949	70,485,435

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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)	\$ 50,691
Issuance of ordinary shares in registered direct offerings, net of issuance expenses in an amount of \$1,150	20,000,000	14,815	(5,965)	-	8,850
Share-based compensation	-	-	250	-	250
Net loss	-	-	-	(5,834)	(5,834)
Balance as of March 31, 2022	116,411,949	\$ 83,602	\$ 84,374	\$ (114,019)	\$ 53,957
Share-based compensation	-	-	274	-	274
Net loss	-	-	-	(4,807)	(4,807)
Balance as of June 30, 2022	116,411,949	\$ 83,602	\$ 84,648	\$ (118,826)	\$ 49,424
Balance as of January 1, 2021	46,239,183	\$ 31,646	\$ 75,715	\$ (90,983)	\$ 16,378
Exercise of warrants, net of issuance expenses in an amount of \$22	24,204,682	18,099	1,120	-	19,219
RSUs vesting	24,395	18	(18)	-	-
Share-based compensation	-	-	73	-	73
Net loss	-	-	-	(3,566)	(3,566)
Balance as of March 31, 2021	70,468,260	\$ 49,763	\$ 76,890	\$ (94,549)	\$ 32,104

RSUs vesting	5,381	4	(4)	-	-
Share-based compensation	-	-	65	-	65
Net loss	-	-	-	(3,918)	(3,918)
Balance as of June 30, 2021	70,473,641	\$ 49,767	\$ 76,951	\$ (98,467)	\$ 28,251

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

	Six months ended June 30,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (10,641)	\$ (7,484)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	159	89
Share-based compensation	525	138
Financial income, net	(239)	(36)
Changes in assets and liabilities items:		
Increase in prepaid and other current assets and non-current assets	(152)	(508)
Increase in trade accounts payable, accruals and other current liabilities	320	27
Decrease in employees and payroll accruals	(293)	(62)
(Decrease) increase in royalties provision	(25)	35
Net cash used in operating activities	\$ (10,346)	\$ (7,801)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(323)	(218)
Investment in short-term bank and other deposits	(13,000)	(8,814)
Net cash used in investing activities	\$ (13,323)	\$ (9,032)
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	8,850	—
Net cash provided by financing activities	\$ 8,850	\$ 19,219
Net increase in cash, cash equivalents and restricted cash	(14,819)	2,386
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	\$ 11,988	\$ 10,439

	Six months ended June 30,	
	2022	2021
<u>Supplemental disclosure of non-cash flow information</u>		
Purchase of property and equipment included in accounts payable and accrued expenses	38	59
Financing fees included in other account payable and accruals	—	291
Assets acquired under operating lease	167	916
<u>Supplemental disclosure of cash flow information:</u>		
Cash paid for taxes	3	7
Interest received	138	24

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

<https://ir.check-cap.com/2022-08-31-Check-Cap-Reports-Second-Quarter-2022-Financial-Results-and-Provides-a-Corporate-Update>