

Check-Cap Reports First Quarter 2023 Financial Results

ISFIYA, Israel, May 11, 2023 /PRNewswire/ -- Check-Cap Ltd. (the "Company" or "Check-Cap") (NASDAQ: CHEK), 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, 2023.

Recent Highlights:

• In March 2023, the Company announced that it has determined that the efficacy results of its calibration studies did not meet its internal goal in order to proceed to the powered portion of the U.S. pivotal study and that the initiation of the powered portion of the U.S. pivotal study was temporarily postponed. As a result, the Company is executing a plan of action, including a dialogue with. the U.S. Food and Drug Administration ("FDA") to amend the U.S. pivotal study protocol, as part of an investigational device exemption (IDE) supplement submission.

"We are actively executing on our plan to optimize the design of the pivotal U.S. trial in collaboration with the FDA, and continue to enrepatients in our calibration studies," said Alex Ovadia, chief executive officer of Check-Cap. "In the first quarter of 2023 we also continue our efforts to activate new clinical trial sites in the U.S. while initiating cost reductions which we expect will extend our cash runway into the fourth quarter of 2024."

Financial Results for the First Quarter Ended March 31, 2023

Research and development expenses, net, were \$3.7 million for the three months ended March 31, 2023 compared to \$4.1 million for the same period in 2022, a decrease of \$0.4 million.

The decrease is primarily due to \$0.4 million reduction in salary and related expenses, mainly as a result of a reduction in bonus expenses and currency exchange rate fluctuation.

General and administrative expenses were \$1.2 million for the three months ended March 31, 2023, compared to \$1.8 million for the same period in 2022, a decrease of \$0.6 million. The decrease is primarily due to a \$0.4 million decrease in professional services, a \$0. million decrease in salary and related expenses, mainly as a result of a reduction in bonus expenses and a \$0.1 million decrease in other general expenses, mainly associated with directors' and officers' liability insurance.

Operating loss was \$4.9 million for the three months ended March 31, 2023, compared to an operating loss of \$5.9 million for the same period in 2022.

Finance income, net, was approximately \$0.4 million for the three months ended March 31, 2023, compared to \$51,000 for the same period in 2022, an increase of approximately \$0.35 million. The increase in finance income, net is primarily due to an income on short-term deposits, mainly due to the increase of interest rates, recorded for the three months ended March 31, 2023.

Net loss was \$4.4 million for the three months ended March 31, 2023, compared to \$5.8 million for the same period in 2022.

Cash and cash equivalents, restricted cash and short-term bank deposits as of March 31, 2023 were \$37.4 million as compared to \$42.1 million as of December 31, 2022.

The number of outstanding ordinary shares as of March 31, 2023 was 5,847,838.

About Check-Cap

Check-Cap is a clinical stage medical diagnostics company aiming to redefine colorectal cancer (CRC) screening through the introductic 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 he 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, 2022 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)

Assets	March 31, 2023		December 31, 2022	
Current assets				
Cash and cash equivalents	\$	16,460	\$	4,090
Restricted cash	Ψ	357	Ψ	352
Short-term bank deposit		20,533		37,609
Prepaid expenses and other current assets		1.153		579
Total current assets		38,503		42,630
Non-current assets				
Property and equipment, net		1,696		1,751
Operating leases		1,115		1,060
Total non-current assets		2,811		2,811
Total assets	\$	41,314	\$	45,441
Liabilities and shareholders' equity Current liabilities Accounts payable and accruals Trade Other Employees and payroll accruals Operating lease liabilities Other current liabilities Total current liabilities Royalties provision Operating lease liabilities Total non-current liabilities	\$	1,184 644 1,314 368 55 3,565 109 615 724	\$	952 802 1,261 337 56 3,408
Shareholders' equity Share capital, Ordinary shares 48 NIS par value (18,000,000 authorized shares as of March 31, 2023 and December 31, 2022; 5,847,838 and 5,844,463 shares issued and outstanding as of March 31,2023 and December 31, 2022, respectively) Additional paid-in capital		83,710 85,050		83,664 84,941
Accumulated deficit Total shareholders' equity		(131,735) 37,025		(127,293 41,312
Total liabilities and shareholders' equity	\$	41,314	\$	45,441

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

Three months ended March 31,

		2023	2022
Research and development expenses, net	\$	3,671	\$ 4,128
General and administrative expenses		1,179	1,757
Operating loss		4,850	 5,885
Finance Income (loss), net	_	408	 51
Net loss for the period	\$	4,442	\$ 5,834
Loss per share:			
Net loss per ordinary share basic and			
diluted	_	0.76	 1.13
Weighted average number of ordinary shares outstanding - basic and diluted	5	5,846,206	5,151,201

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 shareholder: equity
Balance as of January 1, 2023	5,844,463 \$	83,664 \$	84,941	\$ (127,293)	\$ 41,31
Share-based compensation	-	_	156	-	15
RSUs vesting	3,375	46	(46)	-	
Net loss	· -	-	-	(4,442)	(4,442
Balance as of March 31, 2023	5,847,838 \$	83,710 \$	85,051	\$ (131,735)	\$ 37,02

	Number of ordinary shares	Amoun	t	Additional paid-in capital	l Accumulated deficit			Accumulated			Total areholders equity
Balance as of January 1, 2022 Issuance of ordinary shares and warrants in March 2022 registered direct offering, net of issuance expenses in an	.,,	\$ 68,787	' \$	90,089	\$	(108,185)	\$	50,69			
amount of \$1,150	1,000,000	14,815	5	(5,965)		-		8,85			
Share-based compensation	-			250		-		25			
Net loss	-			-		(5,834)		(5,834			
Balance as of March 31, 2022	5,840,089	\$ 83,602	\$	84,374	\$	(114,019)	\$	53,95°			

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

	Three m Ma	onth rch	
	2023		2022
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	\$ (4,442)	\$	(5,834)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Depreciation	95		76
Share-based compensation	156		250
Financial income, net	(23)		(51)
Changes in assets and liabilities items:			
Increase in prepaid and other current assets and non-current assets	(579)		(18)
Increase in trade accounts payable, accruals and other current liabilities	96		389
Increase in employees and payroll accruals	55		296
Increase in royalties provision	14		3
Net cash used in operating activities	\$ (4,628)	\$	(4,889)

CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(65)	(200)
Changes in short-term deposits	17,068	(18,999)
Net cash provided by (used in) investing activities	\$ 17,003	\$ (19,199)
CASH FLOWS FROM FINANCING ACTIVITIES		
Exercise of warrants into ordinary shares, net of issuance expenses	_	_
Issuance of ordinary shares in the registered direct offerings, net of issuance expenses	-	8,894
Net cash provided by financing activities	\$ -	\$ 8,894
Net (decrease) increase in cash, cash equivalents and restricted cash	12,375	(15,194)
Cash, cash equivalents and restricted cash at the beginning of the period	4,442	26,807
Cash, cash equivalents and restricted cash at the end of the period	\$ 16.817	\$ 11.613

 ${\it Logo-https://mma.prnewswire.com/media/820848/Check_Cap_Logo.jpg} \\ {\it SOURCE Check-Cap Ltd.} \\$

Additional assets available online Photos (1)

 $\underline{https://ir.check-cap.com/2023-05-11-Check-Cap-Reports-First-Quarter-2023-Financial-Results}$