



Check-Cap Reports Third Quarter 2021 Financial Results and Corporate Update

ISFIYA, Israel, Nov. 3, 2021 /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 third quarter and nine months ended September 30, 2021.

Third Quarter and Recent Highlights:

- Strengthened balance sheet through gross proceeds of \$35 million in a registered direct offering completed in July 2021. The Company believes that it has sufficient capital to fund its ongoing operations and plans, including the U.S. pivotal study, until well into 2023.
- Strengthened clinical team with the appointment of Dr. Hanit Brenner-Lavie as Vice President of Clinical Affairs and by additional qualified clinical employees. Dr. Brenner-Lavie is leading the Company's overall clinical strategy and its implementation, including the execution of the planned U.S. pivotal trial.
- Expanded C-Scan manufacturing capacity and on-premise production line.
- Continued patient enrollment and data collection at Israeli sites, to further enable optimization of C-Scan's functionality and patient experience ahead of the U.S. pivotal trial.
- Granting of new U.S. patent covering the C-Scan® proprietary tracking technology that enables real time tracking of the capsule and its activation only when it moves throughout the colon. This functionality allows for optimal scanning along the gastrointestinal (GI) tract while maintaining low energy consumption during the procedure. The patent also covers the capsule positioning data recording for the C-Scan analysis suite, which enables gastroenterologists to make a clinical decision and generate a report with their diagnosis and recommendations. This patent will expire in May 2034. Corresponding patents were issued in Japan and China and patents were approved for granting in Europe and Israel.

"This past quarter we have been actively focused on meeting our critical objectives to advance towards the initiation of the U.S. pivotal trial," said Alex Ovadia, chief executive officer of Check-Cap. "The expansion of our manufacturing capacity and the entire production process is expected to secure the robust supply chain of C-Scan devices during the trial. The hire of Dr. Brenner has further strengthened our clinical team to support initiation and management of the planned U.S. pivotal trial."

Mr. Ovadia added, "In addition, our team has continued to build and fortify our patent portfolio ahead of global product commercialization. The recent granting of the patent covering our proprietary tracking technology along with our total patent portfolio secure our exclusive rights to our technology worldwide and enhances shareholder value."

Financial Results for the Third Quarter Ended September 30, 2021

Research and development expenses were \$3.0 million for the three months ended September 30, 2021, compared to \$2.7 million for the same period in 2020. The increase is primarily due to a \$0.3 million increase in salary and related expense and a \$0.1 million increase in material and subcontractors' expenses, offset in part by a \$0.1 million grant received from the Israel Innovation Authority, which reduced research and development expenses.

General and administrative expenses were \$1.2 million for the three months ended September 30, 2021, compared to \$1.0 million for the same period in 2020. The increase is primarily due to a \$0.15 million increase in other general expenses and a \$0.05 million increase in salary and related expense.

Operating loss was \$4.3 million for the three months ended September 30, 2021, compared to \$3.6 million for the same period in 2020.

Finance income was \$22,000 for the three months ended September 30, 2021, compared to \$13,000 for the same period in 2020.

Net loss was \$4.2 million for the three months ended September 30, 2021, compared to \$3.6 million for the same period in 2020.

Cash and cash equivalents, restricted cash and short-term bank deposits as of September 30, 2021 were \$56.8 million, compared with \$29.3 million as of June 30, 2021 and \$18.1 million as of December 31, 2020. During the

first quarter of 2021, certain warrant holders exercised warrants to purchase an aggregate 24,204,682 ordinary shares, which had been issued in 2020, at exercise prices ranging from \$0.75-\$0.80, which generated total gross proceeds of approximately \$19.2 million to the Company. In July 2021, the Company completed the sale of 25,925,926 of the Company's ordinary shares and accompanying short-term warrants to purchase up to an aggregate of 25,925,926 of the Company's ordinary shares in a registered direct offering, which resulted in gross proceeds to the Company of \$35.0 million or approximately \$31.8 million net of offering expenses. The Company believes that it has sufficient capital to fund its ongoing operations and plans until well into 2023.

The number of outstanding ordinary shares as of September 30, 2021 was 96,404,949. As of November 2, 2021, the number of the Company's outstanding ordinary shares was 96,404,949.

Financial Results for the Nine Months Ended September 30, 2021

Research and development expenses were \$8.2 million for the nine months ended September 30, 2021, compared to \$7.2 million for the same period in 2020. The increase is primarily due to a \$0.8 million increase in salary and related expense and a \$0.7 million increase in material and subcontractors' expenses, offset in part by a \$0.3 million grant received from the Israel Innovation Authority, which reduced research and development expenses, and a \$0.2 million decrease in other expenses.

General and administrative expenses were \$3.5 million for the nine months ended September 30, 2021, compared to \$2.8 million for the same period in 2020. The increase is primarily due to a \$0.2 million increase in salary and related expense, a \$0.5 million increase in other general expenses mainly associated with directors and officers insurance liability and a \$0.1 million increase in professional services expenses, offset in part by \$0.1 million decrease in share-based compensation.

Operating loss was \$11.7 million for the nine months ended September 30, 2021, compared to \$10.0 million for the same period in 2020.

Finance income was \$18,000 for the nine months ended September 30, 2021, compared to \$62,000 for the same period in 2020.

Net loss was \$11.7 million for the nine months ended September 30, 2021, compared to \$9.9 million for the same period in 2020.

Net cash used in operating activities was \$11.9 million for the nine months ended September 30, 2021, compared to \$9.6 million for the same period in 2020.

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 significantly increase screening adherence worldwide and 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. Unlike other capsule technologies, 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.

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, 2020 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)

	September 30, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	39,607	7,703
Restricted cash	350	350
Short-term bank deposit	16,812	10,079
Prepaid expenses and other current assets	1,117	285
Total current assets	57,886	18,417
Non-current assets		
Property and equipment, net	1,565	823
Operating lease	1,124	398
Total non-current assets	2,689	1,221
Total assets	60,575	19,638
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable and accruals		
Trade	1,288	862
Other	501	345
Employees and payroll accruals	1,547	1,510
Operating lease liabilities	328	264
Total current liabilities	3,664	2,981
Non-current liabilities		
Royalties provision	178	154
Operating lease liabilities	792	125
Total non-current liabilities	970	279
Shareholders' equity		
Share capital, Ordinary shares, 2.4 NIS par value (360,000,000 authorized shares as of September 30, 2021 and December 31, 2020; 96,404,949 and 46,239,183 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively)	68,782	31,646
Additional paid-in capital	89,867	75,715
Accumulated deficit	(102,708)	(90,983)
Total shareholders' equity	55,941	16,378

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

	Nine months ended September 30,		Three months ended September 30,	
	2021	2020	2021	2020
Research and development expenses, net	8,223	7,177	3,036	2,664
General and administrative expenses	3,520	2,822	1,227	967
Operating loss	11,743	9,999	4,263	3,631
Finance Income, net	18	62	22	11
Loss before income tax	11,725	9,937	4,241	3,618
Net loss for the period	11,725	9,937	4,241	3,618
Loss per share:				
Net loss per ordinary share basic and diluted	0.15	0.40	0.04	0.09
Weighted average number of ordinary shares outstanding - basic and diluted	78,238,314	25,017,699	95,853,149	41,518,821

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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, 2021	46,239,183	\$ 31,646	\$ 75,715	\$ (90,983)	\$ 16,378
Exercise of warrants, net of issuance expenses					
an amount of \$22	24,204,682	\$ 18,099	\$ 1,120	-	\$ 19,219
Issuance of ordinary shares and warrants in the July Financing, net of issuance expenses in an amount of \$3,199	25,925,926	\$ 19,011	\$ 12,790		\$ 31,801
RSU's vesting	35,158	\$ 26	(26)		
Share-based compensation	-	-	\$ 268		\$ 268
Net loss	-	-	-	\$ (11,725)	\$ (11,725)
Balance as of September 30, 2021	96,404,949	\$ 68,782	\$ 89,867	\$ (102,708)	\$ 55,941

Balance as of January 1, 2020	8,272,908	\$ 5,407	\$ 77,964	\$ (77,137)	\$ 6,234
Issuance of ordinary shares in private placement, net of issuance expenses in an amount of approximately \$30	2,720,178	\$ 1,894	\$ 2,837	-	\$ 4,731
Issuance of ordinary shares and warrants in the April - May 2020 Financings, net of issuance expenses in an amount of \$ 1,361	19,166,670	\$ 13,039	\$ (2,900)		\$ 10,139
Issuance of ordinary shares and warrants in a warrant exercise financing, net of Issuance expenses in an amount of \$920	16,054,223	\$ 11,290	\$ (2,578)	-	\$ 8,715
RSU's vesting	19,317	\$ 12	\$ (12)	-	
Share-based compensation	-	-	\$ 317	-	\$ 317
Net loss	-	-	-	\$ (9,937)	(9,937)
Balance as of September 30, 2020	46,233,296	\$ 31,642	\$ 75,628	\$ (87,074)	\$ 20,196

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 June 30, 2021	70,473,641	\$ 49,767	\$ 76,951	\$ (98,467)	\$ 28,251
Issuance of ordinary shares and warrants in the July Financing, net of issuance expenses in an amount of \$3,199	25,925,926	\$ 19,011	\$ 12,790		\$ 31,801
RSU's vesting	5,382	\$ 4	(4)		-
Share-based compensation	-	-	\$ 130		\$ 130
Net loss	-	-	-	\$ (4,241)	\$ (4,241)
Balance as of					

September 30, 2021	96,404,949	\$ 68,782	\$ 89,867	\$ (102,708)	\$ 55,941
Balance as of June 30, 2020	30,172,943	\$ 20,348	\$ 78,110	\$ (83,546)	\$ 15,002
Issuance of ordinary shares and warrants in a warrant exercise financing, net of Issuance expenses in an amount of \$920	16,054,223	\$ 11,290	\$ (2,578)	-	\$ 8,712
RSU's vesting	6,130	\$ 4	\$ (4)	-	-
Share-based compensation	-	-	\$ 100	-	\$ 100
Net loss	-	-	-	\$ (3,618)	(3,618)
Balance as of September 30, 2020	46,233,296	\$ 31,642	\$ 75,628	\$ (87,074)	\$ 20,196


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

	Nine months ended September 30,	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	(11,725)	(9,937)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	139	107
Share-based compensation	268	317
Financial income, net	(47)	(27)
Changes in assets and liabilities items:		
Decrease (increase) in prepaid and other current assets and non-current assets	(819)	106
Increase (decrease) in trade accounts payable, accruals and other current liabilities	243	(295)
Increase in employees and payroll accruals	37	106
Increase in royalties provision	24	6
Net cash used in operating activities	(11,880)	(9,617)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(743)	(293)
Investment in short-term bank and other deposits	(6,700)	(15,003)
Net cash provided by (used in) investing activities	(7,443)	(15,296)
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	32,008	
Issuance of ordinary shares in private placement, net of issuance expenses	-	4,731
Issuance of ordinary shares in the registered direct offerings, net of issuance expenses		10,139
Issuance of ordinary shares and warrants in a warrant exercise financing, net of issuance expenses	-	8,712
Net cash provided by financing activities	51,227	23,582
Net increase (decrease) in cash, cash equivalents and restricted cash	31,904	(1,331)
Cash, cash equivalents and restricted cash at the beginning of the period	8,053	8,035
Cash, cash equivalents and restricted cash at the end of the period	39,957	6,704

Supplemental disclosure of non-cash flow information:

Purchase of property and equipment included in accounts payable and accrued expenses	133	20
Assets acquired under operating leases	968	140
Financing fees included in account payable	207	

SOURCE Check-Cap Ltd.

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

<https://ir.check-cap.com/2021-11-03-Check-Cap-Reports-Third-Quarter-2021-Financial-Results-and-Corporate-Update>