



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

ISFIYA, Israel, Nov. 30, 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 third quarter and nine months ended September 30, 2022.

Third Quarter and Recent Highlights:

- Continued effort to expand number of U.S. sites that will participate in the calibration and statistically powered portions of the U.S. pivotal study of C-Scan. In parallel, the Company has significantly increased the enrollment pace of average risk patients in the Israeli sites, contributing to the calibration portion of the study. The calibration portion of the study is designed to provide further optimization of C-Scan functionality and patient experience towards the statistically powered portion of the U.S. pivotal study. The required lead time to activate new sites in the U.S. is still longer than expected. Also, patient recruitment rate in the activated U.S. sites is still lower than expected. Consequently, the Company has initiated an extensive patient outreach effort, expected to expedite the enrollment pace within the upcoming months. Assuming sites' activation and calibration proceeds as planned, the Company continues to expect the second part of the U.S. pivotal study to start in mid-2023.
- On November 23, 2022, the Company effected a reverse share split of the Company's ordinary shares at the ratio of 1-for-20, such that each twenty (20) ordinary shares, par value NIS 2.40 per share, consolidated into one (1) ordinary share, par value NIS 48.00. The first date the Company's ordinary shares commenced trading on the Nasdaq Capital Market after implementation of the reverse split was Friday, November 25, 2022. Following the implementation of the reverse split, the Company's authorized share capital is comprised of 18 million ordinary shares. Issued and outstanding shares are approximately 5.8 million ordinary shares, from approximately 116 million ordinary shares previously. In addition, a proportionate adjustment was made to the per share exercise price and the number of shares issuable upon the exercise of all outstanding options and warrants entitling the holders to purchase ordinary shares.

"During the third quarter, we have significantly accelerated the pace of patient enrollment in Israel, following an extensive patient outreach campaign which brought high interest and response from average risk patients. In our effort to expand U.S. site participation, our clinical team is working to implement similar patient outreach strategies as those in Israel, which we believe will help accelerate patient enrollment pending IRB approvals," said Alex Ovadia, chief executive officer of Check-Cap. "We have also scaled-up our manufacturing, as well as engagement with key suppliers, which further enables the Company to secure and sustain the entire production process and robust supply chain of C-Scan devices during the trial."

Financial Results for the Third Quarter Ended September 30, 2022

Research and development expenses were \$3.6 million for the three months ended September 30, 2022, compared to \$3.0 million for the same period in 2021. The increase is primarily due to (i) an increase of approximately \$0.3 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 clinical related expenses and regulatory consultants. The Company expects that clinical expenses will increase in the upcoming quarters as it progresses in its ongoing U.S. pivotal study.

General and administrative expenses were \$1.4 million for the three months ended September 30, 2022, compared to \$1.2 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 \$5.0 million for the three months ended September 30, 2022, compared to \$4.3 million for the same period in 2021.

Net finance income was \$0.3 million for the three months ended September 30, 2022, compared to \$22,000 for the same period in 2021.

Net loss was \$4.7 million for the three months ended September 30, 2022, compared to \$4.2 million for the same period in 2021.

Cash and cash equivalents, restricted cash and short-term bank deposits as of September 30, 2022 were \$46.0 million, compared with \$50.2 million as of June 30, 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 Nine Months Ended September 30, 2022

Research and development expenses were \$11.3 million for the nine months ended September 30, 2022, compared to \$8.2 million for the same period in 2021. The increase is primarily due to (i) an increase of approximately \$1.5 million in salary and related expenses, mainly as a result of increased employee head count, (ii) an increase of approximately \$1.0 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 nine months ended September 30, 2021.

General and administrative expenses were \$4.5 million for the nine months ended September 30, 2022, compared to \$3.5 million for the same period in 2021. The increase is primarily due to a \$0.4 million increase in professional services, a \$0.3 million increase in other general expense mainly associated with directors' and officers' liability insurance, and a \$0.3 million increase in share-based compensation.

Operating loss was \$15.8 million for the nine months ended September 30, 2022, compared to \$11.7 million for the same period in 2021.

Net finance income was \$0.4 million for the nine months ended September 30, 2022, compared to \$18,000 for the same period in 2021.

Net loss was \$15.4 million for the nine months ended September 30, 2022, compared to \$11.7 million for the same period in 2021.

Net cash used in operating activities was \$14.6 million for the nine months ended September 30, 2022, compared to \$11.9 million for the same period in 2021.

Basis of Presentation

The financial information for the three and nine months ended September 30, 2022 included in this press release doesn't reflect the impact of the reverse split which became effective on November 25, 2022.

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, Ph.D.
Account Supervisor - Europe
LifeSci Communications
mrroucomolina@lifescicomms.com

CHECK CAP LTD

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

	September 30, 2022 Unaudited	December 31, 2021 Audited
Assets		
Current assets		
Cash and cash equivalents	\$ 9,348	\$ 26,457
Restricted cash	354	350
Short-term bank deposit	36,249	25,104
Prepaid expenses and other current assets	591	839
Total current assets	46,542	52,750
Non-current assets		
Property and equipment, net	1,846	1,793
Operating leases	1,159	1,116
Total non-current assets	3,005	2,909
Total assets	\$ 49,547	\$ 55,659
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable and accruals		
Trade	\$ 849	\$ 1,050
Other	600	680
Employees and payroll accruals	1,834	1,961
Other current liabilities	198	-

Operating lease liabilities	3,853	4,849
Total current liabilities		
Non-current liabilities		
Royalties provision	101	132
Operating lease liabilities	687	795
Total non-current liabilities	788	927
Shareholders' equity		
Share capital, Ordinary shares, 2.4 NIS par value (360,000,000 authorized shares as of September 30, 2022 and December 31, 2021, respectively; 116,483,029 and 96,411,949 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively)	83,653	68,787
Additional paid-in capital	84,852	90,089
Accumulated deficit	(123,580)	(108,185)
Total shareholders' equity	44,925	50,691
Total liabilities and shareholders' equity	<u>\$ 49,547</u>	<u>\$ 55,659</u>

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,	
	2022	2021	2022	2021
Research and development expenses, net	\$ 11,315	\$ 8,223	\$ 3,641	\$ 3,036
General and administrative expenses	4,504	3,520	1,404	1,227
Operating loss	15,819	11,743	5,045	4,263
Finance income, net	424	18	291	22
Loss before income tax	15,395	11,725	4,754	4,241
Net loss for the period	\$ 15,395	\$ 11,725	\$ 4,754	\$ 4,241
Loss per share:				
Net loss per ordinary share basic and diluted	\$ 0.14	\$ 0.15	\$ 0.04	\$ 0.04
Weighted average number of ordinary shares outstanding - basic and diluted	111,884,046	78,238,314	116,454,150	95,853,149

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)	\$ 50,691
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
RSUs vesting	71,080	51	(51)	-	-
Share-based compensation	-	-	779	-	779
Net loss	-	-	-	(15,395)	(15,395)

Balance as of September 30, 2022	116,483,029	\$ 83,653	\$ 84,852	\$ (123,580)	\$ 44,925
---	--------------------	------------------	------------------	---------------------	------------------

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
---	------------	--------	-------	---	--------

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
--	------------	--------	--------	---	--------

RSUs 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
---	-------------------	------------------	------------------	---------------------	------------------

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, 2022	116,411,949	\$ 83,602	\$ 84,648	\$ (118,826)	\$ 49,424
RSU's vesting	71,080	\$ 51	(51)		-
Share-based compensation	-	-	255		\$ 255
Net loss	-	-	-	\$ (4,754)	\$ (4,754)
Balance as of September 30, 2022	116,483,029	\$ 83,653	\$ 84,852	\$ (123,580)	\$ 44,925
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

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, 2022 2021	
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (15,395)	\$ (11,725)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	254	139
Share-based compensation	779	268
Financial income, net	(295)	(47)
Changes in assets and liabilities items:		
Decrease (Increase) in prepaid and other current assets and non-current assets	248	(819)
Increase in trade accounts payable, accruals and other current liabilities	6	243
(Decrease) Increase in employees and payroll accruals	(127)	37
(Decrease) increase in royalties provision	(30)	24
Net cash used in operating activities	\$ (14,560)	\$ (11,880)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(395)	(743)
Investment in short-term bank and other deposits	(11,000)	(6,700)
Net cash used in investing activities	\$ (11,395)	\$ (7,443)
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	32,008
Net cash provided by financing activities	\$ 8,850	\$ 51,227
Net (decrease) increase in cash, cash equivalents and restricted cash	(17,105)	31,904
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	\$ 9,702	\$ 39,957

**Nine months ended
September 30,
2022 2021**

Supplemental disclosure of non-cash flow information


Purchase of property and equipment included in accounts payable and accrued expenses	89	133
Financing fees included in other account payable and accruals	—	207
Assets acquired under operating lease	307	968

Supplemental disclosure of cash flow information:

Cash paid for taxes	23	26
Interest received	377	25

Logo - https://mma.prnewswire.com/media/820848/Check_Cap_Logo.jpg

SOURCE Check-Cap Ltd.

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

<https://ir.check-cap.com/2022-11-30-Check-Cap-Reports-Third-Quarter-2022-Financial-Results-and-Provides-a-Corporate-Update>