Check-Cap Reports Fourth Quarter and Full Year 2021 Financial Results

Company anticipates initiation of the first part of its U.S. pivotal study in April 2022

ISFIYA, Israel, April 7, 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 firs 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 fourth quarter and full year ended December 31, 2021.

2021 and Recent Highlights:

Clinical Progress: In February 2022, the U.S. Food and Drug Administration (FDA) approved the Company's amended Investigational Device Exemption (IDE) application, enabling initiation of the U.S. pivotal study. The firs part of the pivotal study will focus on device calibration and enhancement of C-Scan algorithms and is anticipate to begin in April 2022. The second part of the trial, anticipated to begin in Q4 2022, will compare performance of C-Scan to traditional colonoscopy. This second comparative portion of the study will be analyzed for statistical significance and will serve as the basis for the Company's filing of FDA approval in the U.S. The Compa also continues patient enrollment and data collection at Israeli sites, to further enable optimization of C-Scan's functionality and patient experience in parallel to the U.S. pivotal trial.

Strengthened Manufacturing Capacity: In 2021, the Company expanded the C-Scan manufacturing capacity and on-premise production line to ensure optimized execution of the U.S. pivotal study.

Expanded Clinical Team: In 2021, the Company strengthened its clinical team with the appointment of Dr. Han Brenner-Lavie as vice president of Clinical Affairs and of 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.

Strengthened the Balance Sheet: Cash and cash equivalents, restricted cash and short-term bank deposits a of December 31, 2021 were $51.9 million. 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 t first quarter of 2024.

Intellectual Property: In 2021, the Company was granted four new patents, including a new U.S. patent coveri the C-Scan® proprietary tracking technology that enables real time tracking of the capsule and its activation onl 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.

Breakthrough Device Designation: In early 2021, the FDA approved the Company's Breakthrough Device Designation, strengthening C-Scan's recognition as an alternative method to address the significant unmet need for patient-friendly CRC screening options.

Regulatory Renewals: In late 2021, the European Medical Device Regulation (MDR) issued a renewal of the Company's CE mark approval valid until December 1, 2026. This is a regulatory achievement for the Company, among the first medical device companies to comply with the strict requirements of this new advanced directive. The updated MDR CE approval not only permits Check-Cap to commercialize C-Scan in Europe but provides furth external validation of the Company's quality systems. Additionally, the Company received renewal from the Israe Ministry of Health, the Medical Device Division (AMAR) for marketing of C-Scan in Israel. While currently the Company remains focused primarily on the U.S. market, both renewals enable Check-Cap to continue to explore opportunities to launch C-Scan in multiple international markets.

"2021 was a productive year for Check-Cap as we made progress towards the initiation of the U.S. pivotal trial of Scan, including advancing the manufacturing process, optimizing our device, and expanding the clinical team in the past year," said Alex Ovadia, chief executive officer of Check-Cap. "C-Scan aims to address issues associated with low adherence to preventive screenings with colonoscopies. We look forward to advancing the U.S. pivotal trial imminently to continue gathering clinical evidence of the potential of C-Scan to detect polyps before they ma

turn into cancer, through a more-patient friendly option. We believe C-Scan has the potential to redefine colorect cancer screening in the future and we are excited to potentially bringing this option to the millions of people worldwide."

Financial Results for the Fourth Quarter Ended December 31, 2021

Research and development expenses, net, were $4.1 million for the three months ended December 31, 2021 compared to $2.8 million for the same period in 2020. The increase is primarily due to (i) an increase of approximately $0.5 million in salary and related expenses, mainly as a result of the expansion in employee head count and currency exchange rate fluctuation, (ii) an increase of approximately $0.4 million in other research and development expenses including clinical expenses, (iii) a $0.4 million increase in material expenses, and (iv) an increase of approximately $0.1 million in share-based compensation.

The increase in research and development expenses, net between 2021 and 2020 was offset in part by a $0.1 million grant from the Israel Innovation Authority (the "IIA").

General and administrative expenses were $1.5 million for the three months ended December 31, 2021, compare to $1.1 million for the same period in 2020. The increase is primarily due to a $0.2 million increase in other general expenses, mainly associated with directors' and officers' liability insurance, a $0.1 million increase in salaries and related expenses and a $0.1 million increase in professional services.

Operating loss was $5.6 million for the three months ended December 31, 2021, compared to an operating loss o $3.9 million for the same period in 2020.

Net finance income was $101,000 for the three months ended December 31, 2021, compared to $24,000 for the same period in 2020.

Net loss was $5.5 million for the three months ended December 31, 2021, compared to $3.9 million for the same period in 2020.

Cash and cash equivalents, restricted cash and short-term bank deposits as of December 31, 2021 were $51.9 million as compared to $18.1 million as of December 31, 2020. 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 expenses 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 December 31, 2021 was 96,411,949. As of April 6, 2022, the number of outstanding ordinary shares was 116,411,949.

Financial Results for the Twelve Months Ended December 31, 2021

Research and development expenses, net, were $12.3 million for the twelve months ended December 31, 2021, compared to $10.0 million for the same period in 2020. The increase in research and development, net expenses between 2021 and 2020 was primarily due to (i) an increase of approximately $1.3 million in salary and related expenses, mainly as a result of an expansion in employee head count and currency exchange rate fluctuation, (ii) a $1.2 million increase in material expenses, (iii) an increase of approximately $0.16 million in share-based compensation, and (iv) an increase of approximately $0.3 million in other research and development expenses including clinical expenses. The increase in research and development expenses, net between 2021 and 2020 wa offset in part by a $0.17 million decrease in subcontractor and consultants and a $0.43 million grant from the IIA.

General and administrative expenses were $5.0 million for the twelve months ended December 31, 2021, compared to $3.9 million for the same period in 2020. The increase in general and administrative expenses is primarily due to a $0.3 million increase in salaries and related expenses, a $0.1 million increase in professional services expenses and a $0.7 million increase in other general expenses, mainly associated with directors' and officers' liability insurance, offset in part by a $0.1 million decrease in share-based compensation expenses.

Operating loss was $17.3 million for the twelve months ended December 31, 2021, compared to $13.9 million for the same period in 2020.

Finance income, net, was $119,000 for the twelve months ended December 31, 2021, compared to $86,000 for th same period in 2020.

Net loss was $17.2 million for the twelve months ended December 31, 2021, compared to $13.8 million for the same period in 2020.

Net cash used in operating activities was $16.3 million for the twelve months ended December 31, 2021,

compared to $13.1 million for the same period in 2020.

A copy of the Company's annual report on Form 20-F for the year ended December 31, 2021 has been filed with the U.S. Securities and Exchange Commission at www.sec.gov and posted on the Company's investor relations website at http://ir.check-cap.com/home. The Company will deliver a hard copy of its annual report, including its complete audited consolidated financial statements, free of charge, to its shareholders upon request to Mira Rosenzweig, chief financial officer, at mira.rosenzweig@check-cap.com.

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. Th 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 trave 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- 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
mroucomolina@lifescicomms.com

CHECK CAP LTD.
CONSOLIDATED BALANCE SHEETS

(U.S. dollars in thousands except share data)

	December 31, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 26,457	$ 7,703
Restricted cash	350	350
Short-term bank deposit	25,104	10,079
Prepaid expenses and other current assets	839	285
Total current assets	**52,750**	**18,417**
Non-current assets		
Property and equipment, net	1,793	823
Operating leases	1,116	398
Total non-current assets	**2,909**	**1,221**
Total assets	$ **55,659**	**$ 19,638**
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable and accruals		
Trade	$ 1,050	$ 862
Other	680	345
Employees and payroll accruals	1,961	1,510
Operating lease liabilities	350	264
Total current liabilities	**4,041**	**2,981**
Non-current liabilities		
Royalties provision	132	154
Operating lease liabilities	795	125
Total non-current liabilities	**927**	**279**
Shareholders' equity		
Share capital, Ordinary shares, 2.4 NIS par value (360,000,000 authorized shares as of December 31 31, 2021 and 2020; 96,411,949 and 46,239,183 shares issued and outstanding as of December 31, 2021 and 2020, respectively)	68,787	31,646
Additional paid-in capital	90,089	75,715
Accumulated deficit	(108,185)	(90,983)
Total shareholders' equity	**50,691**	**16,378**
Total liabilities and shareholders' equity	**$ 55,659**	**$ 19,638**

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

	Twelve months ended December 31,		Three months ended December 31,	
	2020	2021	2020	2021
Research and development expenses, net	$ 12,349	$ 10,008	$ 4,126	$ 2,83
General and administrative expenses	4,972	3,924	1,452	1,10
Operating loss	**17,321**	**13,932**	**5,578**	**3,93**
Finance Income, net	119	86	101	2
Net loss for the period	$ **17,202**	$ **13,846**	$ **5,477**	$ **3,90**
Loss per share:				
Net loss per ordinary share basic and				

diluted	0.21	0.46	0.06	0.0
Weighted average number of ordinary shares outstanding - basic and diluted	**82,807,556**	**30,351,368**	**96,408,753**	**46,236,42**

CHECK-CAP LTD.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. dollars in thousands)

	Year ended December 31,		Three months ended December 31,	
	2021	**2020**	**2021**	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES				
Net loss	$ (17,202)	$ (13,846)	$ (5,477)	$ (3,909)
Adjustments required to reconcile net loss to net cash used in operating activities:				
Depreciation	205	148	66	41
Share-based compensation	491	408	223	91
Financial expense, net	-	7	47	34
Changes in assets and liabilities items:				
Decrease (increase) in prepaid and other current assets and non-current assets	(549)	106	270	-
Increase (decrease) in trade accounts payable, accruals and other current liabilities	362	(317)	119	(22)
Increase in employees and payroll accruals	451	409	414	303
Decrease in royalties provision	(22)	(28)	(46)	(34)
Net cash used in operating activities	**$ (16,264)**	**$ (13,113)**	**$ (4,384)**	**$ (3,496)**
CASH FLOWS FROM INVESTING ACTIVITIES				
Purchase of property and equipment	(1,006)	(379)	(263)	(86)
Proceeds from (Investment in) short-term bank and other deposits	(15,000)	(10,072)	(8,300)	4,931
Net cash provided by (used in) investing activities	**$ (16,006)**	**$ (10,451)**	**$ (8,563)**	**$ 4,845**
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	31,801	10,139	(207)	-
Options exercise	4	-	4	-
Issuance of ordinary shares and warrants in the Warrant Exercise Transaction, net of issuance expenses	-	8,712	-	-
Issuance of ordinary shares in the private placement, net of issuance expenses	-	4,731	-	-
Net cash provided by financing activities	**$ 51,024**	**$ 23,582**	**$ (203)**	**$ -**
Net increase (decrease) in cash, cash equivalents and restricted cash	**18,754**	**18**	**(13,150)**	**1,349**
Cash, cash equivalents and restricted cash at the beginning of the period	**8,053**	**8,035**	**39,957**	**6,704**
Cash, cash equivalents and restricted cash at the end of the period	**$ 26,807**	**$ 8,053**	**$ 26,807**	**$ 8,053**

SOURCE Check-Cap Ltd.

Additional assets available online: Photos (1)

https://ir.check-cap.com/2022-04-07-Check-Cap-Reports-Fourth-Quarter-and-Full-Year-2021-Financial-Results