



Check-Cap Reports Third Quarter 2020 Financial Results and Corporate Highlights

Submitted Investigational Device Exemption (IDE) application to the FDA for Pivotal Study of C-Scan®

ISFIYA, Israel, Nov. 18, 2020 [/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, today announced financial results for the third quarter and nine months ended September 30, 2020 and corporate highlights.

Third Quarter and Recent Highlights:

- Investigational Device Exemption (IDE) application submitted to the U.S. Food and Drug Administration (FDA) on November 18, 2020 for pivotal study of C-Scan.
- Continuing preparation for the U.S. pivotal study including progress in establishing supporting device manufacturing, supply chain and quality controls, while initiating the substantial expansion of the clinical dataset on average risk patients at leading Israeli sites.
- Strengthened balance sheet through gross proceeds of \$9.6 million in a warrant exercise financing in July 2020.

"The IDE submission constitutes a major milestone towards the initiation of our U.S. pivotal study," said Alex Ovadia, chief executive officer of Check-Cap. "We plan to provide a further investor update on the timelines for the initiation of the U.S. pivotal study, expected in 2021, following guidance from the FDA."

Mr. Ovadia added "The Check-Cap team remains laser-focused on the Company's goal of advancing C-Scan towards final clinical stages and market acceptance as a patient-friendly colorectal cancer (CRC) screening option for the detection of pre-cancerous polyps before they may transform into cancer."

"Despite the increasing rates of CRC in recent years, especially in the younger population, screening rates remain low mostly due to the invasiveness of the colonoscopy procedure and the required bowel preparation. Non-invasive biomarker tests currently available or in development, such as fecal or liquid biopsy tests, demonstrate low sensitivity in detecting pre-cancerous polyps. There is a great unmet need for a patient-friendly screening option that can help detect polyps before they may turn into cancer and prevent this disease."

COVID-19 Corporate Update

The Company has experienced disruptions to its operations as a result of the COVID-19 pandemic. During the third quarter of 2020, infection rates in Israel began to significantly increase and toward the end of the third quarter, the government mandated a lockdown for the second time this year. The Company has implemented several measures according to the Israel Ministry of Health's guidelines, including remote working whenever possible, physical separation between employees and daily employee health monitoring.

It is still too early to assess the full impact of the COVID-19 outbreak, but the COVID-19 pandemic has affected the Company's ability to initiate its planned pivotal study and commence pilot sales in Israel and Europe in its original timeframe. The extent to which the COVID-19 pandemic shall impact the Company's operations and planned timelines will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration and severity of the outbreak, the impact on the global economy, the impact of any further waves of COVID-19 and the actions that may be required to contain the COVID-19 pandemic or treat its impact. In particular, the continued spread of COVID-19 globally could materially adversely impact the Company's operations and workforce, including its research and clinical trials and its ability to continue raising capital. It could also affect the operations of key governmental agencies, such as the FDA, which may delay the Company's development plans, and could result in the inability of its suppliers to deliver components or raw materials on a timely basis or at all, each of which in turn could have a material adverse impact on its business, financial condition and result of operation.

Financial Results for the Third Quarter Ended September 30, 2020

Research and development expenses were approximately \$2.7 million for the three months ended September 30, 2020, unchanged from the same period in 2019. The main fluctuations were primarily a decrease of approximately \$0.2 million in clinical expenses associated with the pilot study in the U.S. and post CE study in 2019, and a decrease of approximately \$0.2 million in other research and development expenses. The foregoing decrease was offset in part by an increase of approximately \$0.1 million for materials and approximately \$0.3 million in salaries and related expenses.

General and administrative expenses were approximately \$1.0 million for the three months ended September 30, 2020, compared to approximately \$0.8 million for the same period in 2019. The increase was primarily due to an increase of approximately \$0.1 million in other general expenses and approximately \$0.1 million in salaries and related expenses.

Operating loss was approximately \$3.6 million for the three months ended September 30, 2020, unchanged from the operating loss in the same period in 2019.

Net loss was approximately \$3.6 million for the three months ended September 30, 2020, compared to approximately \$3.5 million for the same period in 2019.

Cash and cash equivalents, restricted cash and short-term bank deposits totaled approximately \$21.7 million as of September 30, 2020, compared with approximately \$16.4 million as of June 30, 2020 and approximately \$8.0 million as of December 31, 2019. During the third quarter of 2020, the Company completed a warrant exercise financing resulting in gross proceeds of approximately \$9.6 million (approximately \$8.7 million net of offering expenses). The Company believes that it has sufficient capital to fund its ongoing operation and plans for approximately the next 12 months.

The number of outstanding ordinary shares as of September 30, 2020 was 46,233,296. As of November 17, 2020, the number of the Company's outstanding ordinary shares was 46,237,551.

Financial Results for the Nine Months Ended September 30, 2020

Research and development expenses were approximately \$7.2 million for the nine months ended September 30, 2020, compared to approximately \$7.7 million for the same period in 2019. The decrease is primarily due to (i) a decrease of approximately \$0.7 million in clinical expenses mainly due to higher expenses for the pilot study in the U.S. and post CE study in 2019, (ii) a decrease of approximately \$0.3 million in other research and development expenses, and (iii) a decrease of approximately \$0.2 million in share-based compensation. The foregoing decrease was offset in part by an increase of approximately \$0.7 million in salaries and related expenses mainly as a result of an expansion in head count and currency exchange rate fluctuation.

General and administrative expenses were approximately \$2.8 million for the nine months ended September 30, 2020, compared to approximately \$2.6 million for the same period in 2019. The increase was primarily due to an increase of approximately \$0.1 million in salaries and related expenses, approximately \$0.1 million in share-based compensation and approximately \$0.2 million in other general expenses, offset in part by a decrease of approximately \$0.2 million in professional services expenses.

Operating loss was approximately \$10.0 million for the nine months ended September 30, 2020, compared to approximately \$10.2 million in the same period in 2019.

Finance income, net was approximately \$62,000 for the nine months ended September 30, 2020, compared to approximately \$215,000 for the same period in 2019. The decrease was mainly due to a decline in interest rates

Net loss was approximately \$9.9 million for the nine months ended September 30, 2020, compared to approximately \$10.0 million for the same period in 2019.

Net cash used in operating activities was approximately \$9.6 million for the nine months ended September 30, 2020, compared to net cash used in operating activities of approximately \$9.5 million for the same period in 2019.

[Financial Tables to Follow]

About Check-Cap

Check-Cap is a clinical stage medical diagnostics company aiming to redefine colorectal cancer (CRC) screening and prevention 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. 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. C-Scan is non-invasive and requires no preparation or sedation, allowing the patients to continue their daily routine with no interruption as the capsule is propelled through the gastrointestinal tract by natural motility.

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, 2019 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 public 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)

	<u>September 30,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
Assets		
Current assets		
Cash and cash equivalents	6,354	7,685
Restricted cash	350	350
Short-term bank deposit	15,016	-
Prepaid expenses and other current assets	288	400
Total current assets	<u>22,008</u>	<u>8,435</u>
Non-current assets		
Property and equipment, net	753	540
Operating leases	424	454
Total non-current assets	<u>1,177</u>	<u>994</u>
Total assets	<u>23,185</u>	<u>9,429</u>
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable and accruals		
Trade	952	989
Other	253	490
Employees and payroll accruals	1,207	1,101
Operating lease liabilities	247	222
Total current liabilities	<u>2,659</u>	<u>2,802</u>
Non-current liabilities		
Royalties provision	188	182
Operating lease liabilities	142	211
Total non-current liabilities	<u>330</u>	<u>393</u>
Shareholders' equity		
Share capital, Ordinary shares, 2.4 NIS par value (90,000,000 authorized shares as of September 30, 2020 and December 31, 2019, respectively; 46,233,296 and 8,272,908 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively)	31,642	5,407
Additional paid-in capital	75,628	77,964
Accumulated deficit	(87,074)	(77,137)
Total shareholders' equity	<u>20,196</u>	<u>6,234</u>
Total liabilities and shareholders' equity	<u>23,185</u>	<u>9,429</u>

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

	<u>Nine months ended September 30,</u>		<u>Three months ended September 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Research and development expenses, net	7,177	7,655	2,664	2,746
General and administrative expenses	2,822	2,567	967	818
Operating loss	<u>9,999</u>	<u>10,222</u>	<u>3,631</u>	<u>3,564</u>
Finance income, net	62	215	13	62
Net loss	<u>9,937</u>	<u>10,007</u>	<u>3,618</u>	<u>3,502</u>
Other comprehensive loss:				
Change in fair value of cash flow hedge	-	13	-	-
Comprehensive loss	<u>9,937</u>	<u>10,020</u>	<u>3,618</u>	<u>3,502</u>
Net loss per ordinary share - basic and diluted	0.40	1.27	0.09	0.42
Weighted average number of ordinary shares outstanding - basic and diluted	<u>25,017,699</u>	<u>7,862,530</u>	<u>41,518,827</u>	<u>8,254,013</u>

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	Other comprehensive loss	Accumulated deficit
Balance as of January 1, 2020	8,272,908	\$ 5,407	\$ 77,964	\$ -	\$ (77,137)
Issuance of ordinary shares in private placement, net of issuance expenses in an amount of approximately \$30	2,720,178	\$ 1,894	\$ 2,837		
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)		
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)		
RSU vesting	19,317	\$ 12	\$ (12)		
Share-based compensation	-	-	\$ 317		
Net loss	-	-	-		\$ (9,937)
Balance as of September 30, 2020	46,233,296	\$ 31,642	\$ 75,628	-	\$ (87,074)

	Number of Ordinary Shares	Amount	Additional paid-in capital	Other comprehensive loss	Accumulated deficit
Balance as of January 1, 2019	5,330,684	\$ 3,456	\$ 72,888	\$ (13)	\$ (63,301)
Issuance of ordinary shares and warrants in the 2019 registered direct offering, net of issuance expenses in an amount of \$987	2,906,376	\$ 1,928	\$ 4,583		
Exercise of warrants into ordinary shares	734	-	-		
RSU vesting	28,268	\$ 18	\$ (18)		
Share-based compensation	-	-	\$ 406		
Other comprehensive loss	-	-	-	\$ 13	
Net loss	-	-	-		\$ (10,007)
Balance as of September 30, 2019	8,266,062	\$ 5,402	\$ 77,859	-	\$ (73,308)

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	Other comprehensive loss	Accumulated deficit	Total shareholders' equity
Balance as of June 30, 2020	30,172,943	\$ 20,348	\$ 78,110	\$ -	\$ (83,456)	\$ 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 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

	Number of Ordinary Shares	Amount	Additional paid-in Capital	Other comprehensive loss	Accumulated deficit	Total shareholders' equity
Balance as of June 30, 2019	8,238,462	\$ 5,384	\$ 77,740	\$ -	\$ (69,806)	\$ 13,318
Exercise of warrants into ordinary shares	734	-	-			-
RSU vesting	26,866	\$ 18	\$ (18)			-
Share-based compensation	-	-	\$ 137			\$ 137
Net loss	-	-	-		\$ (3,502)	\$ (3,502)
Balance as of September 30, 2019	8,266,062	\$ 5,402	\$ 77,859	-	\$ (73,308)	\$ 9,953

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,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss for the period	(9,937)	(10,007)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	107	84
Share-based compensation	317	406
Financial (income) expenses, net	(27)	(45)
Changes in assets and liabilities items:		
Decrease (increase) in prepaid and other current assets and non-current assets	106	(37)
Increase (decrease) in trade accounts payable, accruals and other current liabilities	(295)	104
Increase (decrease) in employees and payroll accruals	106	(24)
Increase in royalties provision	6	7
Net cash used in operating activities	(9,617)	(9,512)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(293)	(131)

Proceeds from (investment in) short-term bank and other deposit	(15,003)	1,673
Net cash used in investing activities	(15,296)	1,542
CASH FLOWS FROM FINANCING ACTIVITIES		
Issuance of ordinary shares and warrants in the 2019 registered direct offering, net of issuance expenses	-	6,511
Issuance of ordinary shares in the private placement, net of issuance expenses	4,731	-
Issuance of ordinary shares and warrants in the 2020 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	23,582	6,511
Net increase (decrease) in cash, cash equivalents and restricted cash	(1,331)	(1,459)
Cash, cash equivalents and restricted cash at the beginning of the period	8,035	8,922
Cash, cash equivalents and restricted cash at the end of the period	6,704	7,463

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

	Nine months ended	
	September 30,	
	2020	2019
Supplemental disclosure of non-cash flow information		
Purchase of property and equipment included in accounts payable and accrued expenses	22	-
Recognition of operating leases and operating lease liabilities from adoption of ASU 2016-02		490
Assets acquired under operating leases	140	106

SOURCE Check-Cap Ltd.

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

<https://ir.check-cap.com/2020-11-18-Check-Cap-Reports-Third-Quarter-2020-Financial-Results-and-Corporate-Highlights>