



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

IDE submission to the FDA for C-Scan® planned for the end of 2020; Initiation of a U.S. pivotal study planned for 2021

ISFIYA, Israel, Aug. 6, 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 second quarter and six months ended June 30, 2020.

Second Quarter and Recent Highlights:

- Strengthened balance sheet through gross proceeds of \$16.3 million in registered direct offerings and a private placement of ordinary shares in the first half of 2020, followed by \$9.6 million in a warrant exercise financing in July 2020. Company believes that it has sufficient capital to fund its ongoing operations and plans for at least the next 12 months.
- Investigational Device Exemption (IDE) submission to the FDA planned for the end of 2020, with initiation of a U.S. pivotal study of C-Scan planned for 2021.

"I am happy with the progress we made during the first six months of 2020 and delighted to observe our team's commitment despite the ongoing global COVID-19 crisis. While some of the measures we took at the beginning of the pandemic slowed our anticipated progress, we have resumed near normal operations, including resuming ongoing collection of clinical data in Israel in the third quarter of 2020, and have been successfully adapting ourselves to the dynamic environment," said Alex Ovadia, chief executive officer of Check-Cap. "We anticipate IDE submission to the FDA by the end of 2020 and continue to refine and advance C-Scan to support initiation of a U.S. pivotal study in 2021. This includes establishing manufacturing capacity, quality infrastructure and collection of substantial additional data on device usability."

Mr. Ovadia added, "We have strengthened our ability to achieve corporate objectives with a total of \$25.8 million raised during 2020. As a result, and despite these challenging times, we believe that we are well-positioned to fund our ongoing operations well into 2021, including our plans toward the initiation of the pivotal U.S. trial, while exploring partnerships with potential strategic industry leaders. There is a significant global unmet need for a non-invasive, preparation-free, colon cancer screening technology to detect polyps before they may transform into colorectal cancer, compared to colonoscopy which is the current standard of care. We truly believe the patient-friendly C-Scan system can increase screening rates globally by eliminating the rigorous and unpleasant preparation that colonoscopy and other tests require," said Alex Ovadia.

COVID-19 Corporate Update

In April 2020, as a consequence of the COVID-19 pandemic, the Company communicated it was taking necessary precautions to ensure the safety and well-being of its employees and their families in accordance with the directive of the Israel Ministry of Health, including enabling the majority of employees to work remotely and the remainder to continue working from the Company's headquarters. In parallel, the Company temporarily suspended interactions between hospitals and healthcare professionals with its employees and clinical trial patients and temporarily implemented several cost saving measures.

As a result of the lifting of many government restrictions to control the spread of COVID-19 and the Company's recent fundraisings, the Company resumed near normal operations including resuming its ongoing collection of clinical data in Israel in the third quarter of 2020 and it continues to implement health and safety measures according to guidelines from the Israel Ministry of Health.

It is too early to assess the full impact of COVID-19, but COVID-19 has affected our ability to initiate our planned pivotal study and commence pilot sales in Israel and Europe in our original timeframe. The extent to which the COVID-19 pandemic impacts 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 a second and any further waves of COVID-19 and the actions that may be required to contain the COVID-19 pandemic or treat its impact.

Financial Results for the Second Quarter Ended June 30, 2020

Research and development expenses were \$2.1 million for the three months ended June 30, 2020, compared to \$2.6 million for the same period in 2019. The decrease is primarily due to (i) a decrease of \$0.3 million in clinical expenses mainly due to suspension of clinical activities in the second quarter of 2020 due to the COVID-19 pandemic, (ii) higher expenses for the pilot study in the U.S and post CE study in 2019, and (iii) a decrease of \$0.2 million in other research and development expenses mainly due to several cost reduction measures implemented by the Company in the second quarter of 2020.

General and administrative expenses remained constant at \$0.9 million for the three months ended June 30, 2020, and three months ended June 30, 2019.

Operating loss was \$2.9 million for the three months ended June 30, 2020, compared to an operating loss of \$3.5 million for the same period in 2019.

Net loss was \$2.9 million for the three months ended June 30, 2020, compared to \$3.4 million for the same period in 2019.

Cash and cash equivalents, restricted cash and short-term bank deposits totaled \$16.4 million as of June 30, 2020, compared with \$9.3 million as of March 31, 2020 and \$8.0 million as of December 31, 2019. During the second quarter of 2020, the Company completed three registered direct offerings resulting in gross proceeds of \$11.5 million (approximately \$10.1 million net of offering expenses). Subsequent to the end of

the second quarter, on July 27, 2020, the Company completed a warrant exercise financing resulting in gross proceeds of \$9.6 million (approximately \$8.7 million net of offering expenses). The Company believes that it has sufficient capital to fund its ongoing operations and plans for at least the next 12 months.

The number of outstanding ordinary shares as of June 30, 2020 was 30,172,943. As of August 4, 2020, the number of our outstanding ordinary shares was 46,231,661.

Financial Results for the Six Months Ended June 30, 2020

Research and development expenses were \$4.5 million for the six months ended June 30, 2020, compared to \$4.9 million for the same period in 2019. The decrease is primarily due to (i) a decrease of \$0.5 million in clinical expenses mainly due to suspension of clinical activities in the second quarter of 2020 due to the COVID-19 pandemic, (ii) higher expenses for the pilot study in the U.S and post CE study in 2019, (iii) a decrease of \$0.2 million in other research and development expenses mainly due to several cost reduction measures implemented by the Company in the second quarter of 2020, and (iv) a decrease of \$0.2 million in share-based compensation. The foregoing decrease was offset in part by an increase of \$0.4 million in salaries and related expenses as a result of an expansion in head count as compared to the same period in 2019.

General and administrative expenses were \$1.9 million for the six months ended June 30, 2020, compared to \$1.7 million for the same period in 2019. The increase was primarily due to an increase of \$0.1 million in share-based compensation and \$0.2 million in other general expenses, offset in part by a decrease of \$0.1 million in professional services expenses.

Operating loss was \$6.4 million for the six months ended June 30, 2020, compared to \$6.7 million in the same period in 2019.

Net loss was \$6.3 million for the six months ended June 30, 2020, compared to \$6.5 million for the same period in 2019.

Net cash used in operating activities was \$6.4 million for the six months ended June 30, 2020, compared to Net cash used in operating activities of \$6.3 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 publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

CHECK CAP LTD

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

	<u>June 30, 2020</u>	<u>December 31 2019</u>
Assets		
Current assets		
Cash and cash equivalents	8,390	7,685
Restricted cash	350	350
Short-term bank deposit	7,656	-
Prepaid expenses and other current assets	503	400
Total current assets	<u>16,899</u>	<u>8,435</u>
Non-current assets		
Property and equipment, net	630	540
Operating leases	347	454
Total non-current assets	<u>977</u>	<u>994</u>
Total assets	<u>17,876</u>	<u>9,429</u>

Liabilities and shareholders' equity**Current liabilities**

Accounts payable and accruals		
Trade	643	989
Other	258	490
Employees and payroll accruals	1,471	1,101
Operating lease liabilities	204	222
Total current liabilities	2,576	2,802

Non-current liabilities

Royalties provision	177	182
Operating lease liabilities	121	211
Total non-current liabilities	298	393

Shareholders' equity

Share capital, Ordinary shares, 2.4 NIS par value (90,000,000 authorized shares as of June 30, 2020 and December 31, 2019, respectively; 30,172,943 and 8,272,908 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively)

Additional paid-in capital	20,348	5,407
Accumulated deficit	78,110	77,964
	(83,456)	(77,137)
Total shareholders' equity	15,002	6,234

Total liabilities and shareholders' equity

	17,876	9,429
--	---------------	--------------

CHECK CAP LTD.**CONSOLIDATED UNAUDITED STATEMENTS OF COMPREHENSIVE LOSS**

(U.S. dollars in thousands, except share and per share data)

	Six months ended June 30,		Three months ended June 30,	
	2020	2019	2020	2019
Research and development expenses, net	4,513	4,909	2,051	2,570
General and administrative expenses	1,855	1,749	898	924
Operating loss	6,368	6,658	2,949	3,494
Finance income, net	49	153	61	139
Loss before income tax	6,319	6,505	2,888	3,355
Taxes on income	-	-	-	-
Net loss	6,319	6,505	2,888	3,355
Other comprehensive loss:				
Change in fair value of cash flow hedge	-	13	-	(4)
Comprehensive loss	6,319	6,518	2,888	3,351
Net loss per ordinary share - basic and diluted	0.38	0.85	0.12	0.41
Weighted average number of ordinary shares outstanding - basic and diluted	16,676,469	7,663,045	23,396,152	8,238,034

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 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
RSU vesting	6,633	4	(4)	-	-	-
Share-based compensation	-	-	123	-	-	123

Net loss											
Balance as of March 31, 2020	10,999,719	\$	7,305	\$	80,920	=	\$	(3,431)	\$	(3,431)	
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		
RSU vesting	6,554	\$	4	\$	(4)				-		
Share-based compensation	-		-	\$	94	-	-	\$	94		
Net loss	-		-		-	-	\$	(2,888)	\$	(2,888)	
Balance as of June 30, 2020	30,172,943	\$	20,348	\$	78,110	\$	-	\$	(83,456)	\$	15,002
Balance as of January 1, 2019	5,330,684	\$	3,456	\$	72,888	\$	(13)	\$	(63,301)	\$	13,030
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	-	-		6,511		
RSU vesting	718		(*)		-				(*)		
Share-based compensation	-		-		83	-	-		83		
Other comprehensive loss	-		-		-	17	-		17		
Net loss	-		-		-	-	(3,150)		(3,150)		
Balance as of March 31, 2019	8,237,778		5,384		77,554	4	(66,451)		16,491		
Share-based compensation	-		-		186				186		
RSU vesting	684		(*)		-	-	-		(*)		
Other comprehensive loss	-		-		-	(4)	-		(4)		
Net loss	-		-		-	-	(3,355)		(3,355)		
Balance as of June 30, 2019	8,238,462		5,384		77,740	-	(69,806)		13,318		

(*) Represents amount less than 1 thousand.

CHECK-CAP LTD.

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

	Six months ended June 30	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss for the period	(6,319)	(6,505)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	68	55
Share-based compensation	217	269
Financial (income) expenses, net	(14)	(32)
Changes in assets and liabilities items:		
Decrease (increase) in prepaid and other current assets and non-current assets	(100)	50
Increase (decrease) in trade accounts payable, accruals and other current liabilities	(591)	(204)
Increase (decrease) in employees and payroll accruals	370	15
Increase (decrease) in royalties provision	(5)	3
Net cash used in operating activities	(6,374)	(6,349)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(140)	(49)
Proceeds from (investment in) short-term bank and other deposit	(7,651)	(370)
Net cash used in investing activities	(7,791)	(419)
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	-
Net cash provided by financing activities	14,870	6,511
Net increase (decrease) in cash, cash equivalents and restricted cash	705	(257)
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	8,740	8,665

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:

Six
months

		ended June 30,
	2020	2019

Supplemental disclosure of non-cash flow information

Purchase of property and equipment included in accounts payable and accrued expenses

Recognition of operating leases and operating lease liabilities from adoption of ASU 2016-02


15	-
-	490

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

SOURCE Check-Cap Ltd.

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

<https://ir.check-cap.com/2020-08-06-Check-Cap-Reports-Second-Quarter-2020-Financial-Results-and-Corporate-Highlights>