



# Check-Cap Reports Second Quarter 2019 Financial Results and Corporate Highlights

## Reported positive final results from post-CE approval study of the C-Scan® System

ISFIYA, Israel, Aug. 7, 2019 /PRNewswire/ -- [Check-Cap Ltd.](#) (the "Company" or "Check-Cap") (NASDAQ: CHEK) (NASDAQ: CHEKW), (NASDAQ: CHEKZ), a clinical stage medical diagnostics company advancing the development of C-Scan®, the first and only preparation-free ingestible capsule based system for the prevention of colorectal cancer through the detection of precancerous polyps, today announced financial results for the second quarter and six months ended June 30, 2019.

### Second Quarter and Recent Highlights:

- Announced positive final results from its post-CE approval study of the C-Scan System. The study met its primary endpoint, achieving sensitivity (ability to correctly identify patients with polyps) of 76% in patients with polyps  $\geq 10$  mm and specificity (ability to correctly identify patients with lack of polyps) of 82% in all patients, compared to FIT that achieved 29% sensitivity and 96% specificity. In addition, the C-Scan System detected all 4 patients (100%) with polyps  $\geq 40$  mm, while FIT detected on 1 of the 4 patients (25%) with polyps  $\geq 40$ mm. Overall, the C-Scan System achieved a sensitivity of 66% in all patients, including patients with polyps  $< 10$ mm, while FIT achieved a sensitivity of 23% for the same population.
- Progressed the U.S. pilot study of the C-Scan System at NYU School of Medicine and Mayo Clinic which is evaluating the safety usability and subject compliance in up to 45 subjects. Results from the U.S. pilot study, if positive, would represent another major milestone towards the initiation of the planned U.S. pivotal study in 2020.
- Appointed Joshua (Shuki) Belkar as Vice President of Operations, bringing more than 20 years of experience managing operations at global medical device companies, including Medtronic and Mazor Robotics.
- Presented a poster at Digestive Disease Week®, entitled "*Swallow and forget*" study: *Prepless X-Ray imaging capsule with enhanced algorithms shows substantial improvement in polyp detection.*"

"During the first half of 2019, we achieved two very significant milestones," said Alex Ovadia, Chief Executive Officer of Check-Cap. "First, we initiated our U.S. pilot study, which, if it yields positive results, will set the stage for a planned pivotal study next year. Second, we reported compelling results from our post-CE approval study, which add to the growing body of evidence demonstrating both the C-Scan System's positive safety profile and its superior clinical performance relative to FIT for pre-cancerous polyp detection. The C-Scan System is highly differentiated as the only preparation-free colon cancer screening alternative, aimed at addressing what is believed to be the primary cause for avoiding standard of care CRC screening, preventing a significant portion of the target population from being screened according to widely accepted clinical guidelines," Mr. Ovadia concluded.

### Financial Results for the Second Quarter Ended June 30, 2019

Research and development expenses, net, were \$2.6 million for the three months ended June 30, 2019, compared to \$1.7 million for the same period in 2018. The increase is primarily due to an increase of \$0.5 million in expenses for the post-CE approval study and ongoing pilot study, as well as an increase of \$0.3 million in salaries and related expenses as a result of expansion in head count and \$0.1 million in share-based compensation.

General and administrative expenses remained consistent at \$0.9 million for the three months ended June 30, 2019, similar to the amount for the same period in 2018.

Operating loss was \$3.5 million for the three months ended June 30, 2019, compared to an operating loss of \$2.7 million for the same period in 2018.

Financial income, net was \$139,000 for the three months ended June 30, 2019, compared to \$30,000 for the same period in 2018. The increase was due to income from interest on bank deposits.

Net loss was \$3.4 million for the three months ended June 30, 2019, compared to \$2.7 million for the same period in 2018.

Cash and cash equivalents, restricted cash and short-term bank deposits totaled \$14.7 million as of June 30, 2019, compared with \$17.3 million at March 31, 2019 and \$14.6 million as of December 31, 2018.

### Financial Results for the Six Months Ended June 30, 2019

Research and development expenses, net were \$4.9 million for the six months ended June 30, 2019, compared to \$3.4 million for the same period in 2018. The increase is primarily due to an increase of \$0.8 million in expenses related to the post-CE approval study and ongoing pilot study, as well as an increase of \$0.4 million in salaries and related expenses as a result of expansion in head count and \$0.2 million in share-based compensation. This increase was partially offset by a \$58,000 grant received from the Israel Innovation Authority.

General and administrative expenses were \$1.7 million for the six months ended June 30, 2019, compared to \$1.4 million for the same period in 2018. The increase was primarily due to an increase of \$0.4 million in share-based compensation and \$0.1 million in professional services. This increase was partially offset by a \$0.2 million decrease in salaries and related expenses.

Operating loss was \$6.7 million for the six months ended June 30, 2019, compared to \$4.8 million in the same period in 2018.

Finance income, net was \$153,000 for the six months ended June 30, 2019, compared to \$9,000 for the same period in 2018. The increase was due to income from interest on bank deposits.

Net loss was \$6.5 million for the six months ended June 30, 2019, compared to \$4.8 million for the same period in 2018.

Net cash used in operating activities was \$6.3 million for the six months ended June 30, 2019, compared to \$4.8 million for the same period in 2018.

The number of outstanding ordinary shares as of June 30, 2019 was 8,238,462. This number includes the 2,906,376 ordinary shares that were issued in the February 2019 registered direct offering.

[Financial Tables to Follow]

## About Check-Cap

Check-Cap is advancing the development of C-Scan® System, the first and only preparation-free ingestible scanning capsule based system for the prevention of colorectal cancer (CRC) through the detection of precancerous polyps. The patient-friendly test has the potential to increase screening adherence and reduce the overall incidence of CRC. The C-Scan System utilizes 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 patient 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 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, 2018 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 BALANCE SHEETS** (U.S. dollars in thousands)

|   | <b>June 30,</b> | <b>December 31,</b> |
|---|-----------------|---------------------|
|   | <b>2019</b>     | <b>2018</b>         |
|   | (unaudited)     | (audited)           |
| <b>Assets</b>                                   |                 |                     |
| <b>Current assets</b>                           |                 |                     |
| Cash and cash equivalents                       | 8,315           | 8,572               |
| Restricted cash                                 | 350             | 350                 |
| Short-term bank deposit                         | 6,044           | 5,643               |
| Prepaid expenses and other current assets       | 370             | 419                 |
| <b>Total current assets</b>                     | <b>15,079</b>   | <b>14,984</b>       |
| <b>Non-current assets</b>                       |                 |                     |
| Property and equipment, net                     | 446             | 452                 |
| Operating leases                                | 423             | -                   |
| <b>Total non-current assets</b>                 | <b>869</b>      | <b>452</b>          |
| <b>Total assets</b>                             | <b>15,948</b>   | <b>15,436</b>       |
| <br><b>Liabilities and shareholders' equity</b> |                 |                     |
| <b>Current liabilities</b>                      |                 |                     |
| Accounts payable and accruals                   |                 |                     |
| Trade   | 855             | 1,113               |
| Other   | 290             | 249                 |
| Employees and payroll accruals                  | 874             | 859                 |
| Operating lease liabilities                     | 187             | -                   |
| <b>Total current liabilities</b>                | <b>2,206</b>    | <b>2,221</b>        |
| <b>Non-current liabilities</b>                  |                 |                     |
| Royalties provision                             | 188             | 185                 |
| Operating lease liabilities                     | 236             | -                   |
| <b>Total non-current liabilities</b>            | <b>424</b>      | <b>185</b>          |
| <b>Shareholders' equity</b>                     |                 |                     |
| Share capital                                   | 5,384           | 3,456               |

|   |               |               |
|---|---------------|---------------|
| Additional paid-in capital                        | 77,740        | 72,888        |
| Accumulated other comprehensive loss              | (69,806)      | (63,301)      |
| Accumulated deficit                               |               |               |
| <b>Total shareholders' equity</b>                 | <u>13,318</u> | <u>13,030</u> |
| <b>Total liabilities and shareholders' equity</b> | <u>15,948</u> | <u>15,436</u> |

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

|  | Six months ended June 30, |              | Three months ended June 30, |              |
|--|---------------------------|--------------|-----------------------------|--------------|
|  | 2019                      | 2018         | 2019                        | 2018         |
| Research and development expenses, net                                     | 4,909                     | 3,357        | 2,570                       | 1,737        |
| General and administrative expenses  | 1,749                     | 1,435        | 924                         | 950          |
| <b>Operating loss</b>  | <u>6,658</u>              | <u>4,792</u> | <u>3,494</u>                | <u>2,687</u> |
| Finance income, net  | 153                       | 9            | 139                         | 30           |
| <b>Loss before income tax</b>  | <u>6,505</u>              | <u>4,783</u> | <u>3,355</u>                | <u>2,657</u> |
| Taxes on income  | -                         | (1)          | -                           | (2)          |
| <b>Net loss</b>  | <u>6,505</u>              | <u>4,782</u> | <u>3,355</u>                | <u>2,655</u> |
| <b>Other comprehensive loss:</b>   |                           |              |                             |              |
| Change in fair value of cash flow hedge                                    | 13                        | -            | (4)                         | -            |
| <b>Comprehensive loss</b>  | <u>6,518</u>              | <u>4,782</u> | <u>3,351</u>                | <u>2,655</u> |
| Net loss per ordinary share - basic and diluted                            | <u>0.85</u>               | <u>1.74</u>  | <u>0.41</u>                 | <u>0.7</u>   |
| Weighted average number of ordinary shares outstanding - basic and diluted | <u>7,663</u>              | <u>2,741</u> | <u>8,238</u>                | <u>3,796</u> |

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

|  | Six months ended<br>June 30, |                 |
|--|------------------------------|-----------------|
|  | 2019                         | 2018            |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES</b>  |                              |                 |
| Net loss for the period  | (6,505)                      | (4,782)         |
| <b>Adjustments required to reconcile net loss to net cash used in operating activities:</b>  |                              |                 |
| Depreciation and amortization  | 55                           | 82              |
| Share-based compensation   | 269                          | (393)           |
| Financial (income) expenses, net   | (32)                         | (18)            |
| Increase in royalties provision  | 3                            | 25              |
| <b>Changes in assets and liabilities items:</b>  |                              |                 |
| Decrease in prepaid and other current assets and non-current assets                          | 50                           | 35              |
| Decrease in trade accounts payable, accruals and other current liabilities                   | (204)                        | (131)           |
| Increase (decrease) in employees and payroll accruals  | 15                           | 288             |
| <b>Net cash used in operating activities</b>   | <b>(6,349)</b>               | <b>(4,894)</b>  |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES</b>  |                              |                 |
| Purchase of property and equipment   | (49)                         | (8)             |
| Investments in short-term bank deposits, net   | (370)                        | (10,000)        |
| <b>Net cash used in investing activities</b>   | <b>(419)</b>                 | <b>(10,008)</b> |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES</b>  |                              |                 |
| Issuance of ordinary shares in the 2018 public offering, net of issuance expenses            | -                            | 17,862          |
| Issuance of ordinary shares in the 2019 registered direct offering, net of issuance expenses | 6,511                        | -               |
| <b>Net cash provided by financing activities</b>   | <b>6,511</b>                 | <b>17,862</b>   |

|   |              |              |
|---|--------------|--------------|
| <b>Net increase (decrease) in cash and cash equivalents and restricted cash</b>     | <b>(257)</b> | <b>2,969</b> |
| <b>Cash and cash equivalents and restricted cash at the beginning of the period</b> | <b>8,922</b> | <b>8,969</b> |
| <b>Cash and cash equivalents and restricted cash at the end of the period</b>       | <b>8,665</b> | <b>9,957</b> |

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

**Supplemental information for Cash Flow:**

|  | <b>Six months ended<br/>June 30,</b> |             |
|--|--------------------------------------|-------------|
|  | <b>2019</b>                          | <b>2018</b> |
| <u>Supplemental disclosure of non-cash flow information</u>                                  |                                      |             |
| Cashless exercise of warrants to purchase ordinary shares into ordinary shares               | -                                    | 9           |
| Purchase of property and equipment   | -                                    | 7           |
| Recognition of operating leases and operating lease liabilities from adoption of ASU 2016-02 | 490                                  | -           |

**Investor Contacts**

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