



Check-Cap Reports Third Quarter 2023 Financial Results and Provides a Corporate Update

Check-Cap shareholders to vote on proposed Business Combination Agreement with Keystone Dental at Annual General Meeting on Monday, December 18th

ISFIYA, Israel, Nov. 27, 2023 /PRNewswire/ -- [Check-Cap Ltd.](#) (the "Company" or "Check-Cap") (NASDAQ: CHEK), today announced financial results and provided a corporate update for the third quarter and nine months ended September 30, 2023.

Check Cup Propose Business Combination Agreement

- In August 2023, Keystone Dental and Check-Cap announced entering into a definitive Business Combination Agreement (the "Business Combination Agreement") under which the stockholders of Keystone Dental will become the majority holders of the combined company. If completed, the business combination will create a public company headquartered in Irvine, CA and focused on advancing commercial execution and market development of Keystone Dental's comprehensive portfolio of implants, full arch restorations, and other tooth replacement solutions, in addition to biomaterial and digital dentistry capabilities. Upon closing of the transaction, the combined company will trade on the NASDAQ under the symbol "KSD." The executive team of Keystone Dental will serve as the executive team of the combined company, led by Melker Nilsson, Keystone's Chief Executive Officer.

Check-Cap has scheduled an Annual General Meeting of Shareholders (the "Meeting") to be held on Monday, December 18, 2023 at 2:00 p.m. (Israel time) at the offices of Check-Cap's Israeli legal counsel, FISCHER (FBC & Co.), located at 146 Menachem Begin Rd., Tel Aviv 6492103, Israel. At the Meeting, investors will be asked to consider and vote on several proposals, including a proposal to approve the Business Combination Agreement. Only shareholders of record at the close of business on November 10, 2023, are entitled to notice of and to vote at the Meeting or at any adjournment thereof.

Keystone Dental Recent Business Development

- **GENESIS ACTIVE™ Implant System Commercial Launch** – Keystone Dental announced the commercial launch of GENESIS ACTIVE™ Implant System, a state-of-the-art surgical and prosthetic solution that is expected to transform how dental professionals approach implant placement and restoration. The system contains an innovative restorative portfolio of dental implant technologies in one system that enables dental professionals to deliver implant treatments with greater efficiency.
- **Nexus Connect Market Launch** – Keystone Dental announced market launch of Nexus Connect, a unique software solution that utilizes proprietary technology and a machine-learning model to analyze implant scan performed with an intraoral scanner. The Nexus Connect employs proprietary 3D computer vision algorithm and geometric processing to detect Nexus Scan Gauges, segment them from tissue, and calculate their positions to ensure the captured data can proceed to prosthetic design. The analysis mechanism is a mathematical regression model based on thousands of completed real-world cases enabling immediate scan data results at the source of capture.
- **Patent for Nexus IOS Solution** – Keystone Dental announced that the United States Patent and Trademark Office (USPTO) has granted Osteon Medical, a subsidiary of Keystone Dental, a patent for the innovative Nexus IOS solution. The Nexus IOS Scan Gauge technology allows implant dentists to perform direct full-arch implant scans using an Intraoral Scanner (IOS) with predictable and passive fitting prosthetic outcomes. This technology replaces the traditionally manual impression-taking process through a faster, cost-effective, and accessible workflow.

Financial Results for the Third Quarter Ended September 30, 2023

In anticipation of the initiation of the strategic development plan, management terminated the majority of the Company's research and development activities. As a result, investment in research and development activities and in clinical trials was reduced to \$30,000 for the three months ended September 30, 2023, compared to \$3.6 million for the same period in 2022. The decrease is primarily comprised of (i) a decrease of approximately \$1.8 million in salary and related expenses and a decrease of \$0.4 million in share-based compensation resulting from

termination of employees (ii) a decrease of \$0.8 million in materials and subcontractors and , (iii) a decrease of approximately \$0.5 million in other research and development expenses, including clinical related expenses and regulatory consultants.

General and administrative expenses were \$2.8 million for the three months ended September 30, 2023, compared to \$1.4 million for the same period in 2022. The increase is primarily due to a \$1.8 million increase in professional services mainly related to legal and advisors' expenses related to the pending transaction with Keystone Dental and strategic activities, offset in part by a \$0.1 million reduction in share-based compensation and a \$0.3 million decrease in other general expenses.

Impairment of fixed assets was \$60,000 for the three months ended September 30, 2023, compared to none for the same period in 2022. The impairment is associated with the reduction in the Company's operating activities.

Operating loss was \$2.9 million for the three months ended September 30, 2023, compared to \$5.0 million for the same period in 2022.

Net finance income was \$0.3 million for the three months ended September 30, 2023, same as in the comparable period in 2022.

Net loss was \$2.6 million for the three months ended September 30, 2023, compared to \$4.7 million for the same period in 2022.

Cash and cash equivalents, restricted cash and short-term bank deposits as of September 30, 2023 were \$28.2 million, compared with \$32.4 million as of June 30, 2023 and \$42.1 million as of December 31, 2022.

Financial Results for the Nine Months Ended September 30, 2023

In anticipation of the initiation of the strategic development plan, management terminated the majority of the Company's research and development activities. As a result, investment in research and development activities and in clinical trials was reduced to \$8.2 million for the nine months ended September 30, 2023, compared to \$11.3 million for the same period in 2022. The decrease is primarily comprised of (i) a decrease of approximately \$1.9 million in salary and related expenses and \$0.5 million decrease in share-based compensation as a result of termination of employees (iii) a decrease of approximately \$0.7 million in materials and subcontractors and other research and development expenses, including clinical related expenses and regulatory consultants, mainly associated with the termination of clinical studies and operations.

General and administrative expenses were \$5.6 million for the nine months ended September 30, 2023, compared to \$4.5 million for the same period in 2022. The increase is primarily due to a \$1.9 million increase in professional services mainly related to legal and advisors' expenses relating to the pending transaction with Keystone Dental and strategic activities, and \$0.1 million in salary and related expenses including directors' fees, offset in part by \$0.3 million reduction in share-based compensation and a \$0.6 million decrease in other general expenses, mainly associated with directors' and officers' liability insurance costs.

Impairment of fixed assets was \$1.4 million for the nine months ended September 30, 2023. Due to the changes in circumstances that indicate that the carrying amount of an asset may not be recoverable, the Company reviewed its long-lived assets for impairment in accordance with ASC 360-10 "Accounting for the Impairment or Disposal of Long-Lived Assets". Therefore, the Company recorded an impairment loss of \$1.4 million.

Operating loss was \$15.2 million for the nine months ended September 30, 2023, compared to \$15.8 million for the same period in 2022.

Net finance income was \$1.3 million for the nine months ended September 30, 2023, compared to \$0.4 million for the same period in 2022. The increase in finance income, net is primarily due to an increase in interest income on short-term deposits of \$0.8 million.

Net loss was \$13.9 million for the nine months ended September 30, 2023, compared to \$15.4 million for the same period in 2022.

Net cash used in operating activities was \$13.4 million for the nine months ended September 30, 2023, compared to \$14.6 million for the same period in 2022.

About Keystone Dental Group:

Keystone Dental is a global commercial-stage medical technology company focused on providing end-to-end tooth replacement solutions for dental practitioners. Headquartered in Irvine, California, and with research and development and manufacturing sites in Caesarea, Israel and Melbourne, Australia, Keystone Dental markets its products worldwide. The Company's product portfolio includes proprietary offerings such as its innovative implant systems Genesis Active, Molaris™ and Prima Plus™ that offer unique solutions to dental practitioners. In addition

the Company also offers an attractive dental implant value brand in Paltop, and a well-regarded portfolio of biomaterials mainly sold under the DYNA brand. Keystone Dental acquired Implant Solutions Pty Ltd ("Osteon") in 2021, adding a comprehensive portfolio of prosthetic solutions on implants and digital workflow capabilities, not least of which is the groundbreaking Nexus iOS digital workflow solution for restoring the fully edentulous patient. For more information, refer to www.keystonedental.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®, a screening test designed to detect polyps before they may transform into colorectal cancer and enable early intervention and cancer prevention. 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, 2022 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.

Participants in the Solicitation

Check-Cap, Keystone Parent and their respective directors and executive officers may be deemed under SEC rule to be participants in the solicitation of proxies from the shareholders of Check-Cap in connection with the business combination. Information about Check-Cap's directors and executive officers is set forth in Check-Cap's Annual Report on Form 20-F for the year ended December 31, 2022 which was filed with the SEC on March 31, 2023. Information about Keystone Dental's directors and executive officers will be set forth in the prospectus (when available). Other information regarding the interests of such individuals, as well as information regarding other persons who may be deemed participants in the business combination, will be set forth in the prospectus, the proxy statement and other relevant materials to be filed or submitted with the SEC when they become available. Investors, Keystone security holders and Check-Cap security holders and other readers should read the prospectus and the proxy statement carefully when they become available before making any voting or investment decision.

No Offer or Solicitation

This communication is not intended to and shall not constitute an offer to buy or sell or the solicitation of an offer to buy or sell any securities, or a solicitation of any vote or approval, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made, except by means of a prospectus meeting the requirements of Section 10 of the U.S. Securities Act of 1933, as amended.

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

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CHECK CAP LTD**CONSOLIDATED UNAUDITED BALANCE SHEETS**

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

	September 30, 2023 Unaudited	December 31, 2022 Audited
<u>Assets</u>		
Current assets		
Cash and cash equivalents	\$ 3,383	\$ 4,090
Restricted cash	130	352
Short-term bank deposit	24,684	37,609
Prepaid expenses and other current assets	577	579
Total current assets	28,774	42,630
Non-current assets		
Property and equipment, net	183	1,751
Operating leases	73	1,060
Total non-current assets	256	2,811
Total assets	\$ 29,030	\$ 45,441
<u>Liabilities and shareholders' equity</u>		
Current liabilities		
Accounts payable and accruals		
Trade	\$ 108	\$ 952
Other	717	802
Employees and payroll accruals	757	1,261
Other current liabilities	23	56
Operating lease liabilities	30	337
Total current liabilities	1,635	3,408
Non-current liabilities		
Royalties provision	-	94
Operating lease liabilities	-	627
Total non-current liabilities	-	721
<u>Shareholders' equity</u>		
Share capital, Ordinary shares, 48 NIS par value (18,000,000 authorized shares as of September 30, 2023 and December 31, 2022, respectively; 5,850,100 and 5,844,463 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively)	83,740	83,664
Additional paid-in capital	84,858	84,941
Accumulated deficit	(141,203)	(127,293)
Total shareholders' equity	27,395	41,312

Total liabilities and shareholders' equity	\$	29,030	\$	45,441
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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,	
	2023	2022	2023	2022
Research and development expenses, net	\$ 8,181	\$ 11,315	\$ 30	\$ 3,64
General and administrative expenses	5,595	4,504	2,833	1,40
Impairment of fixed assets	1,426	-	62	
Operating loss	15,202	15,819	2,925	5,04
Finance Income , net	1,292	424	335	29
Loss before income tax	13,910	15,395	2,590	4,75
Net loss for the period	\$ 13,910	\$ 15,395	\$ 2,590	\$ 4,75
Loss per share:				
Net loss per ordinary share basic and diluted	\$ 2.38	\$ 2.74	\$ 0.44	\$ 0.8
Weighted average number of ordinary shares outstanding - basic and diluted	5,849,189	5,613,696	5,849,756	5,842,20

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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, 2023	5,844,463	\$ 83,664	\$ 84,941	\$ (127,293)	\$ 41,312
RSUs vesting	5,637	76	(76)	-	.
Share-based compensation	-	-	(7)	-	(7
Net loss	-	-	-	(13,910)	(13,910
Balance as of September 30, 2023	5,850,100	\$ 83,740	\$ 84,858	\$ (141,203)	\$ 27,395

Balance as of January 1, 2022	4,840,089	\$ 68,787	\$ 90,089	\$ (108,185)	\$ 50,691
Issuance of ordinary shares and warrants in March 2022 registered direct offerings, net of issuance expenses in an amount of \$1,150					

RSUs vesting	1,009,984	14,855	(5,965)	=	8,850
Share-based compensation	-	-	779	-	779
Net loss	-	-	-	(15,395)	(15,395)
Balance as of September 30, 2022	5,843,653	\$ 83,653	\$ 84,852	\$ (123,580)	\$ 44,925

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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, 2023	5,849,216	\$ 83,728	\$ 85,075	\$ (138,613)	\$ 30,190
RSU's vesting	884	\$ 12	(12)		
Share-based compensation	-	-	(205)		\$ (205)
Net loss	-	-	-	\$ (2,590)	\$ (2,590)
Balance as of September 30, 2023	5,850,100	\$ 83,740	\$ 84,858	\$ (141,203)	\$ 27,395
Balance as of June 30, 2022	5,840,089	\$ 83,602	\$ 84,648	\$ (118,826)	\$ 49,424
RSU's vesting	3,564	\$ 51	(51)	-	
Share-based compensation	-	-	255	-	\$ 255
Net loss	-	-	-	\$ (4,754)	\$ (4,754)
Balance as of September 30, 2022	5,843,653	\$ 83,653	\$ 84,852	\$ (123,580)	\$ 44,925

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CONSOLIDATED UNAUDITED STATEMENTS OF CASH FLOWS

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

	Nine months ended September 30, 2023 2022	
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (13,910)	\$ (15,395)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	190	254
Impairment of fixed assets	1,426	-
Share-based compensation	(7)	779
Financial income, net	374	(295)
Changes in assets and liabilities items:		
Decrease in prepaid and other current assets and non-current assets	37	248
(Decrease) Increase in trade accounts payable, accruals and other current liabilities	(926)	6
Decrease in employees and payroll accruals	(505)	(127)
Decrease in royalties provision	(94)	(30)
Net cash used in operating activities	\$ (13,415)	\$ (14,560)

CASH FLOWS FROM INVESTING ACTIVITIES

Purchase of property and equipment	(83)	(395)
Investment in short-term bank and other deposits	12,569	(11,000)
Net cash used in investing activities	\$ 12,486	\$ (11,395)

CASH FLOWS FROM FINANCING ACTIVITIES

Issuance of ordinary shares in the registered direct offerings, net of issuance expenses	-	8,850
Net cash provided by financing activities	\$ -	\$ 8,850

Net decrease in cash, cash equivalents and restricted cash	(929)	(17,105)
Cash, cash equivalents and restricted cash at the beginning of the period	4,442	26,807
Cash, cash equivalents and restricted cash at the end of the period	\$ 3,513	\$ 9,702

**Nine months ended
September 30,
2023 2022**


Supplemental disclosure of non-cash flow information

Purchase of property and equipment included in accounts payable and accrued expenses	-	89
Assets acquired under operating lease	136	307

Supplemental disclosure of cash flow information:

Cash paid for taxes	2	23
Interest received	1,720	377

SOURCE Check-Cap Ltd.

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

<https://ir.check-cap.com/2023-11-27-Check-Cap-Reports-Third-Quarter-2023-Financial-Results-and-Provides-a-Corporate-Update>