

# INSTITUTIONAL RESEARCH

# Medical Devices

**UPDATE REPORT** 

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## Check-Cap (NASDAQ/CHEK) – Neutral

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Jason Kolbert

#### **Check-Cap: Strategic Alternatives - \$37M in Cash Remains**

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Check-Cap previously announced that the C-scan results failed to meet its target. The company has now backed away from what it said initially, (that it would adapt its clinical plan). The company has hired a bank to evaluate "strategic alternatives" and reduce its employees down to eight. We remain neutral rated.

### **Investment Highlights**

Check-cap updated C-Scan results which failed to meet its target. In May 2022, the company initiated the first part of the U.S. pivotal study of C-Scan, which focuses on device calibration and enhancement of C-Scan algorithms among the average-risk U.S. population. At the same time, to support the calibration portion of the U.S. pivotal study the company continued enrolling average-risk patients in its Israel study.

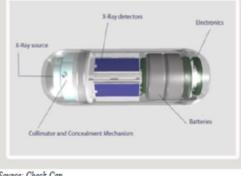
Following an internal assessment of the clinical data collected to date from the calibration studies, the Company has determined that the current efficacy results do not meet its goal in order to proceed to the powered portion of the U.S. pivotal study. As a result, the Company initially adopted a plan of action to conduct additional clinical data analysis in the hopes of approaching the FDA to make amendments to the U.S. pivotal study protocol. It now appears that is not going to happen. The company stated in its press release:

"After further review of additional data and interaction with the FDA on a revised pivotal study protocol together with the anticipated time and investment necessary to further develop the technology, the Company's Board of Directors has determined that it is appropriate to pursue strategic options. In addition, the Company's Board of Directors has approved a reduction in its workforce by approximately 90 percent, to reduce the Company's cash burn, after which the Company expects to have eight remaining employees. In light of these developments, the Company is discontinuing the calibration studies and does not plan on commencing the powered portion of its U.S. pivotal study and plans to concentrate its resources on its essential research activities and strategic alternatives."

**Valuation.** Our valuation is based on the assumed success of the E.U. and U.S. launches of Check-Cap's imaging capsule. We use a 30% probability of success for the E.U. and U.S. approvals and commercialization. The product revenue models then flow into our income statement, which is projected out to 2030. On top of these therapeutic success probabilities, we apply a discount rate (r) of 30% (our highest rate for emerging growth companies), and we assume additional capital raises (dilution).

**Risk Factors:** These include clinical, investment and financial, regulatory, intellectual property, and commercial risk.

# Current Price \$1.95 Price Target NA X-Bay detectors Dectrooks



source. Cneck-Cap		
Stock Data		
52-Week Range	\$1.22 -	\$9.20
Shares Outstanding (mil.)		5.8
Market Capitalization (mil.	)	\$11
Enterprise Value (mil.)		-\$26
Debt to Capital		0%
Book Value/Share		\$10.59
Price/Book		0.3
Average Three Months Tra	ding Volume (K)	16
Insider Ownership		0.1%
Institutional Ownership		2.5%
Short interest (mil.)		0.9%
Dividend / Yield		\$0.00/0.0%





#### **Exhibit 1. Income Statement**

Exhibit 1: Income Statement																	
Check-Cap: Income Statement (\$000)																	
.: YE December 31	2018A	2019A	2020A	2021A	2022A	1Q23A	2Q23E	3Q23E	4Q23E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Product sales																	
Imaging capsule EU	-	-	-		-	-	-	-	-	-	-	-	-	90,129	117,988	137,093	156,459
Imaging capsule US	-	-	-	-	-	-	-	-	-	-	-	-	-	8,540	17,372	44,171	89,849
Total Product Sales	-	-	-	-	-	-	-	-	-	-	-	-		98,669	135,360	181,263	246,309
Expenses																	
Cost of Goods Sold			0	0	0	0	0	0	0	0	0	0	0	24,667	33,840	45,316	61,577
%COGS	S		0%	0%	0%	0%	0%	0%	0%	0%	25%	25%	25%	25%	25%	25%	25%
Research and Development	7,618	10,474	10,008	12,349	14,271	3,671	2,954	3,339	3,468	12,844	11,560	10,404	10,508	10,613	10,719	10,826	10,934
%R&E																	
General and Administrative	3,445	3,595	3,924	4,972	5,763	1,179	1,392	1,573	1,634	6,051	6,354	6,671	7,072	7,496	7,946	8,422	8,928
%SG&/					-						•						·
Total expenses	11.063	14.069	13.932	17.321	20.034	4.850	4.346	4.913	5,102	18.895	17.913	17.075	17.579	42.776	52.504	64.564	81.439
Operating Income (Loss)	(11,063)	(14,069)	(13,932)	(17,321)	(20,034)	(4,850)	(4,346)	(4,913)	(5,102)	(18,895)	(17,913)	(17,075)	(17,579)	55,893	82,855	116,699	164,869
populating moonie (2000)	(11,000)	(11,000)	(10,002)	(17,021)	(20,001)	(1,000)	(1,010)	(1,010)	(0,102)	(10,000)	(11,010)	(11,010)	(11,010)	00,000	02,000	110,000	101,000
Finance income	473	233	86	119	926												
Finance expenses	-																
Total other income	473	233	86	119	926	-	-		-	-	-	-	-	-	-	-	-
Pretax Income	(10,590)	(13,836)	(13,846)	(17,202)	(19,108)	(4,850)	(4,346)	(4,913)	(5,102)	(18,895)	(17,913)	(17,075)	(17,579)	55.893	82.855	116.699	164,869
change in fair value of cash flow hedge	(13)							, , ,			, , ,	, , ,	, , ,		·		·
Income Tax Benefit (Provision)	1	(13)	_	-	_	408	_	_	. /	408	(2,687)	(2,903)	(3,516)	13,973	22,371	35,010	52,758
Tax Rate	•	(1-7)			0%	0%	0%	0%	0%	0%	15%	17%	20%	25%	27%	30%	32%
GAAP Net Income (loss)	(10.602)	(13,823)	(13,846)	(17,202)	(19,108)	(4,442)	(4,346)	(4,913)	(5,102)	(19,303)	(15,226)	(14,172)	(14.063)	41.920	60.484	81.689	112,111
CAPAT NET INCOME (1033)	(10,001)	(10,020)	(13,040)	(17,202)	(13,100)	(4,442)	(4,540)	(4,515)	(3,102)	(13,303)	(13,220)	(14,112)	(14,000)	41,520	00,404	01,003	112,111
GAAP-EPS	(2.61)	(1.73)	(0.63)	0.21	(3.37)	(0.76)	(0.37)	(0.42)	(0.44)	(1.99)	(1.30)	(1.20)	(1.19)	3.53	5.08	6.83	9.34
GAAP EPS (dil)	(2.61)	(1.73)	(0.52)	(0.15)	(3.37)	(0.38)	(0.37)	(0.41)	(0.42)	(1.62)	(1.23)	(1.10)	(1.05)	2.99	4.15	5.39	7.11
Wgtd Avg Shrs (Bas) - '000s	4,058	7,986	30,351	82,807	5,671	5,846	11,669	11,681	11,692	10,222	11,722	11,769	11,816	11,863	11,911	11,958	12,006
Wgtd Avg Shrs (Dil) - '000s	4.058	7.986	47.643	110.550	5,671	11.762	11.879	11.998	12.118	11,939	12,424	12.929	13,454	14.000	14.568	15,160	15,776

Source: Dawson James estimates, company reports

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#### **Risk Analysis**

Clinical Trial Risk. Check-Cap is dependent on the outcome of multiple clinical trials.

**Commercial Risk.** Check-Cap hopes to initially commercialize the device in Europe and Israel, followed by the U.S. There can be no assurances that the company can achieve meaningful market share.

**Financial Risk.** Check-Cap is likely to require additional capital raises before the company can be self-sustaining. There can be no guarantees that the company will be able to raise the needed capital.

**Investment Risk**. Check-Cap is a small capital company, which can translate into high volatility and risk for investors. The company has no revenues and is dependent on the clinical progress of the device.

**Intellectual Property.** Check-Cap may face I.P. challenges, forcing the company to defend its patents or against claims that the company is infringing on other patents.

Regulatory Risk. Check-Cap, even with good clinical data, could face extensive delays and other regulatory setbacks.

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#### **Important Disclosures:**

#### **Price Chart:**



Price target and rating changes over the past three years:

Initiated – Buy – December 5, 2019 – Price Target \$4.00

Update - Buy - March 9, 2020 - Price Target \$4.00

Price Target Change - Buy - April 21, 2020 - Price Target Lowered from \$4.00 to \$2.00

Update – Buy – May 11, 2020 – Price Target \$2.00

Rating change – Neutral – March 17, 2021 – Price Target NA

Update - Neutral - May 12, 2021 - Price Target NA

Update - Neutral - June 30, 2021 - Price Target NA

Update - Neutral - December 16, 2021 - Price Target NA

Update - Buy - February 7, 2022 - Price Target \$1.0

Update - Buy - March 2, 2022 - Price Target \$1.0

Update - Buy - April 7, 2022 - Price Target \$1.0

Update - Buy - July 5, 2022 - Price Target \$1.0

Rating Change – Neutral from Buy – September 15, 2022 - Price Target NA

Update - Neutral - December 8, 2022 - Price Target NA

Update – Neutral – March 22, 2023 – Price Target NA

Update - Neutral - April 5, 2023 - Price Target NA

Update - Neutral - June 7, 2023 - Price Target NA

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- 2) Neutral: The analyst believes the price of the stock is fairly valued for the next 12-18 months:
- 3) **Sell**: The analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

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Current as of 25-May-23

	Company Coverage		Investment Banking	
				% of
Ratings Distribution	# of Companies	% of Total	# of Companies	Totals
Market Outperform (Buy)	26	72%	2	6%
Market Perform (Neutral)	10	28%	1	3%
Market Underperform (Sell)	0	0%	0	0%
Total	36	100%	3	9%

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