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## Check-Cap (NASDAQ/CHEK) – Neutral

March 22, 2023

### Check-Cap – CV Scan Update – Delays, Delays & Delays

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*Check-Cap provided an update in the C-Scan Program. Our take-away is that the program is delayed. From the company's release: "Following our 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." We remain neutral rated.*

### Investment Highlights

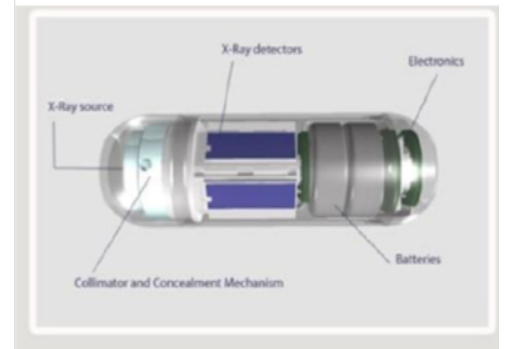
Check-cap updated C-Scan: In May 2022 the company initiated the first part of the U.S. pivotal study of C-Scan, which focuses on device calibration and enhancement of C-Scan algorithms among the average risk U.S. population. At the same time, to support the calibration portion of the U.S. pivotal study 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 adopted a plan of action that includes conducting additional clinical data analysis and approaching the FDA to make amendments to the U.S. pivotal study protocol that are expected to be part of an IDE supplement submission to the FDA, and which are subject to FDA approval. In addition, the Company plans to continue conducting its calibration studies, albeit at a slower pace, to collect additional clinical data and the Company is also implementing a cost reduction plan, in order to extend its cash runway. The initiation of the powered portion of the U.S. pivotal study that was expected in mid-2023 is therefore temporarily postponed.

**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) in our final projected fully diluted share count of 160M (2030). We then apply these projections to our Free Cash Flow to the Firm or FCFF, discounted EPS or dEPS, and sum-of-the-parts or SOP models, which are equal-weighted, averaged, and rounded to the nearest whole number to derive our 12-month price target. These metrics point to fair value in the \$4-\$5 range, which supports our Neutral rating.

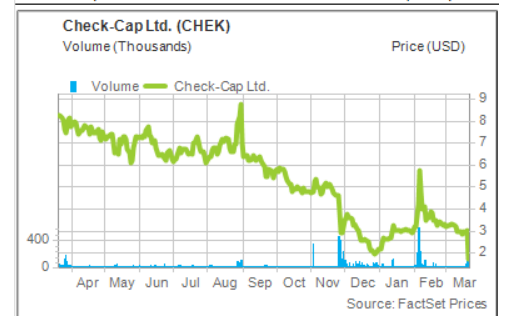
**Risk Factors:** These include clinical, investment and financial, regulatory, intellectual property, and commercial risk.

Current Price **\$1.75**  
Price Target **NA**



Source: Check-Cap

Stock Data			
52-Week Range	\$1.60	-	\$9.20
Shares Outstanding (mil.)	5.8		
Market Capitalization (mil.)	\$10		
Enterprise Value (mil.)	-\$36		
Debt to Capital	0%		
Book Value/Share	\$10.59		
Price/Book	1.3		
Average Three Months Trading Volume (K)	71		
Insider Ownership	0.1%		
Institutional Ownership	1.6%		
Short interest (mil.)	0.5%		
Dividend / Yield	\$0.00/0.0%		



**Exhibit 1. U.S. Model**

Capsule Endoscopy - US	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
<b>Colorectal Cancer Screenings</b>	115,169,082	115,975,266	116,787,092	117,604,602	118,427,834	119,256,829	120,091,627	120,932,268	121,778,794	122,631,246
<b>% Not screened or Not Current (34%)</b>	<b>39,157,488</b>	<b>39,431,590</b>	<b>39,707,611</b>	<b>39,985,565</b>	<b>40,265,464</b>	<b>40,547,322</b>	<b>40,831,153</b>	<b>41,116,971</b>	<b>41,404,790</b>	<b>41,694,624</b>
Market penetration	0.00%				0.00%	0.00%	0.10%	0.20%	0.50%	1.00%
Total addressable patients	-	-	-	-	-	-	40,831	82,234	207,024	416,946
Patients with insurance	85%	85%	85%	85%	85%	85%	85%	85%	85%	85%
Total eligible patients	-	-	-	-	-	-	34,706	69,899	175,970	354,404
Tests per patient	1	1	1	1	1	1	1	1	1	1
Total tests needed	-	-	-	-	-	-	34,706	69,899	175,970	354,404
Cost per test	\$ 662	\$ 695	\$ 729	\$ 766	\$ 804	\$ 812	\$ 820	\$ 828	\$ 837	\$ 845
Increase in price	5%	5%	5%	5%	5%	1%	1%	1%	1%	1%
<b>Sales (\$000)</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ 28,467</b>	<b>\$ 57,906</b>	<b>\$ 147,235</b>	<b>\$ 299,497</b>
Risk adjustment	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%
<b>US Revenue (\$000)</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ 8,540</b>	<b>\$ 17,372</b>	<b>\$ 44,171</b>	<b>\$ 89,849</b>

Source: Dawson James

**Exhibit 2. E.U. Model**

Capsule Endoscopy - EU	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
<b>Colorectal Cancer Screenings</b>	57,859,662	58,264,680	58,672,533	59,083,240	59,496,823	59,913,301	60,332,694	60,755,023	61,180,308	61,608,570
<b>% Not screened or Not Current (34%)</b>	<b>57,859,662</b>	<b>58,264,680</b>	<b>58,672,533</b>	<b>59,083,240</b>	<b>59,496,823</b>	<b>59,913,301</b>	<b>60,332,694</b>	<b>60,755,023</b>	<b>61,180,308</b>	<b>61,608,570</b>
Market penetration			0.00%	0.00%	0.00%	0.00%	1.00%	1.30%	1.50%	1.70%
Total addressable patients	-	-	-	-	-	-	603,327	789,815	917,705	1,047,346
Patients with insurance	85%	85%	85%	85%	85%	85%	85%	85%	85%	85%
Total eligible patients	-	-	-	-	-	-	512,828	671,343	780,049	890,244
Tests per patient	1	1	1	1	1	1	1	1	1	1
Total tests needed	-	-	-	-	-	-	512,828	671,343	780,049	890,244
Cost per test	\$ 541	\$ 552	\$ 563	\$ 574	\$ 586	\$ 586	\$ 586	\$ 586	\$ 586	\$ 586
Increase in price	2%	2%	2%	2%	2%	0%	0%	0%	0%	0%
<b>Sales (\$000)</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ 300,430</b>	<b>\$ 393,293</b>	<b>\$ 456,976</b>	<b>\$ 521,531</b>
Risk adjustment	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%
<b>EU Total Sales (\$000)</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ 90,129</b>	<b>\$ 117,988</b>	<b>\$ 137,093</b>	<b>\$ 156,459</b>
Royalty rate	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
<b>EU Revenue (\$000)</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ 90,129</b>	<b>\$ 117,988</b>	<b>\$ 137,093</b>	<b>\$ 156,459</b>
<b>Total Revenue (\$000)</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ 98,669</b>	<b>\$ 135,360</b>	<b>\$ 181,263</b>	<b>\$ 246,309</b>

Source: Dawson James

**Exhibit 1. Income Statement**

Check-Cap: Income Statement (\$000)																	
YE December 31	2018A	2019A	2020A	2021A	1Q22A	2Q22A	3Q22A	4Q22E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
<b>Product sales</b>																	
Imaging capsule EU	-	-	-	-	-	-	-	-	-	-	-	-	-	90,129	117,988	137,093	156,459
Imaging capsule US	-	-	-	-	-	-	-	-	-	-	-	-	-	8,540	17,372	44,171	89,849
<b>Total Product Sales</b>	-	-	-	-	-	-	-	-	-	-	-	-	-	<b>98,669</b>	<b>135,360</b>	<b>181,263</b>	<b>246,309</b>
<b>Expenses</b>																	
Cost of Goods Sold			0	0	0	0	0	0	0	0	0	0	0	24,667	33,840	45,316	61,577
	<b>%COGS</b>		<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>25%</b>	<b>25%</b>	<b>25%</b>	<b>25%</b>	<b>25%</b>	<b>25%</b>	<b>25%</b>
Research and Development	7,618	10,474	10,008	12,349	4,128	3,545	3,641	3,001	11,114	10,003	9,002	8,102	8,183	8,265	8,348	8,431	8,515
	<b>%R&amp;D</b>																
General and Administrative	3,445	3,595	3,924	4,972	1,757	1,343	1,404	1,477	5,469	5,743	6,030	6,331	6,711	7,114	7,541	7,993	8,473
	<b>%SG&amp;A</b>																
<b>Total expenses</b>	<b>11,063</b>	<b>14,069</b>	<b>13,932</b>	<b>17,321</b>	<b>5,885</b>	<b>4,888</b>	<b>5,045</b>	<b>4,477</b>	<b>16,583</b>	<b>15,745</b>	<b>15,032</b>	<b>14,433</b>	<b>14,894</b>	<b>40,046</b>	<b>49,728</b>	<b>61,740</b>	<b>78,565</b>
Operating Income (Loss)	(11,063)	(14,069)	(13,932)	(17,321)	(5,885)	(4,888)	(5,045)	(4,477)	(16,583)	(15,745)	(15,032)	(14,433)	(14,894)	58,623	85,631	119,523	167,743
Finance income	473	233	86	119	51	81	291	-	-	-	-	-	-	-	-	-	-
Finance expenses	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Total other income</b>	<b>473</b>	<b>233</b>	<b>86</b>	<b>119</b>	<b>51</b>	<b>81</b>	<b>291</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Pretax Income</b>	<b>(10,590)</b>	<b>(13,836)</b>	<b>(13,846)</b>	<b>(17,202)</b>	<b>(5,834)</b>	<b>(4,807)</b>	<b>(4,754)</b>	<b>(4,477)</b>	<b>(16,583)</b>	<b>(15,745)</b>	<b>(15,032)</b>	<b>(14,433)</b>	<b>(14,894)</b>	<b>58,623</b>	<b>85,631</b>	<b>119,523</b>	<b>167,743</b>
change in fair value of cash flow hedge	(13)																
Income Tax Benefit (Provision)	1	(13)	-	-	-	-	-	-	(1,575)	(2,255)	(2,454)	(2,979)	(2,979)	14,656	23,120	35,857	53,678
<b>Tax Rate</b>					<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>10%</b>	<b>15%</b>	<b>17%</b>	<b>20%</b>	<b>25%</b>	<b>27%</b>	<b>30%</b>	<b>32%</b>	
<b>GAAP Net Income (loss)</b>	<b>(10,602)</b>	<b>(13,823)</b>	<b>(13,846)</b>	<b>(17,202)</b>	<b>(5,834)</b>	<b>(4,807)</b>	<b>(4,754)</b>	<b>(4,477)</b>	<b>(16,583)</b>	<b>(14,171)</b>	<b>(12,777)</b>	<b>(11,980)</b>	<b>(11,915)</b>	<b>43,967</b>	<b>62,511</b>	<b>83,666</b>	<b>114,065</b>
<b>GAAP-EPS</b>	<b>(2.61)</b>	<b>(1.73)</b>	<b>(0.63)</b>	<b>0.21</b>	<b>(0.06)</b>	<b>(0.04)</b>	<b>(0.04)</b>	<b>(0.38)</b>	<b>(0.52)</b>	<b>(1.21)</b>	<b>(1.09)</b>	<b>(1.02)</b>	<b>(1.01)</b>	<b>3.71</b>	<b>5.25</b>	<b>7.00</b>	<b>9.50</b>
GAAP EPS (dil)	(2.61)	(1.73)	(0.52)	(0.15)	(0.06)	(0.04)	(0.04)	(0.38)	(0.19)	(1.19)	(1.03)	(0.93)	(0.89)	3.14	4.29	5.52	7.23
Wgtd Avg Shrs (Bas) - '000s	4,058	7,986	30,351	82,807	102,634	116,411	116,454	11,645	86,786	11,675	11,721	11,768	11,815	11,863	11,910	11,958	12,006
Wgtd Avg Shrs (Dil) - '000s	4,058	7,986	47,643	110,550	102,634	116,411	116,454	11,645	86,786	11,939	12,424	12,929	13,454	14,000	14,568	15,160	15,776

Source: Dawson James estimates, company reports

## 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.

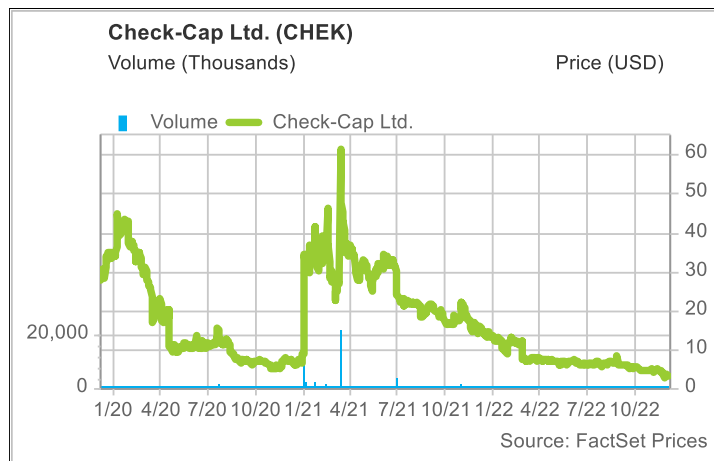
**Investment Risk.** Check-Cap is a small capital company, which can translate into high volatility and risk for investors. The company has no revenues and is dependent on the clinical progress of the device.

**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.

## 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

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- 1) **Buy:** The analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months;
- 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 17-Mar-23

	Company Coverage		Investment Banking	
<b>Ratings Distribution</b>	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	25	69%	1	3%
Market Perform (Neutral)	11	31%	2	6%
Market Underperform (Sell)	1	3%	0	0%
Total	36	100%	3	9%

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