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## Check-Cap (NASDAQ/CHEK) – Lowering to Neutral

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### Check-Cap Reports 2Q22 ~ \$50M in Cash on Balance Sheet – Reverse Split is Coming –Lowering to Neutral

Check-Cap spent \$4.8M in the 2<sup>nd</sup> quarter 2022 and closed the period with approximately \$50M in cash. In August the company received shareholder approval to reverse the stock (1 for 10 or 20). We feel it's prudent to lower our buy rating to Neutral and remove our price target until we have greater clarity on what exactly the company is going to do.

### Investment Highlights

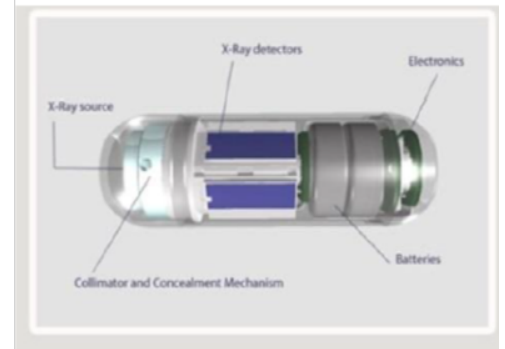
**Delays have plagued the U.S. Pivotal trial.** The company has begun the first part of the U.S. pivotal study but enrollment is stated as “slow”. Recall that the first part of the study plans to focus on device calibration and enhancement of C-Scan algorithms. The company is enrolling average-risk patients in Israel, to further optimize C-Scan functionality and the patient experience. The required lead time to activate new sites as well as to recruit patients in the U.S. has been longer than expected. The Company is continuing to work on activating new sites while at the same time calibrating the C-Scan device and its algorithms. Assuming sites' activation and calibration proceeds as planned, the Company now expects the second part of the U.S. pivotal study to start in mid-2023 versus prior statements of 4<sup>th</sup> Quarter this year.

**Europe too:** In late 2021, the European Medical Device Regulation (MDR) issued a renewal of the Company's C.E. mark approval for an additional five years. The updated MDR CE approval permits Check-Cap to commercialize C-Scan in Europe. The renewal enables the company to continue to explore opportunities to launch C-Scan in other international markets.

**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. As we are stepping our rating down from Buy to Neutral, we remove our target valuation. We expect to reassess the decision once we have greater clarity on the planned reverse stock split.

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

Current Price **\$0.32**  
 Price Target **NA**



Source: Check-Cap

Stock Data			
52-Week Range	\$0.29	-	\$1.31
Shares Outstanding (mil.)	116.4		
Market Capitalization (mil.)	\$37		
Enterprise Value (mil.)	-\$13		
Debt to Capital	0%		
Book Value/Share	\$0.53		
Price/Book	1.3		
Average Three Months Trading Volume (K)	201		
Insider Ownership	1.2%		
Institutional Ownership	0.4%		
Short interest (mil.)	1.1%		
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	3Q22E	4Q22E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
<b>Product sales</b>																	
Imaging capsule EU	-	-	-	-	-	-	-	-	-	-	-	-	-	150,215	196,646	228,488	260,766
Imaging capsule US	-	-	-	-	-	-	-	-	-	-	-	-	-	8,540	17,372	44,171	89,849
<b>Total Product Sales</b>	-	-	-	-	-	-	-	-	-	-	-	-	-	158,755	214,018	272,659	350,615
<b>Expenses</b>																	
Cost of Goods Sold			0	0	0	0	0	0	0	0	0	0	0	39,689	53,505	68,165	87,654
	<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	2,890	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	1,422	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>4,312</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>55,068</b>	<b>69,393</b>	<b>84,589</b>	<b>104,642</b>
Operating Income (Loss)	(11,063)	(14,069)	(13,932)	(17,321)	(5,885)	(4,888)	(4,312)	(4,477)	(16,583)	(15,745)	(15,032)	(14,433)	(14,894)	103,687	144,625	188,070	245,973
Finance income	473	233	86	119	51	81	-	-	-	-	-	-	-	-	-	-	-
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>-</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>(4,312)</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>103,687</b>	<b>144,625</b>	<b>188,070</b>	<b>245,973</b>
change in fair value of cash flow hedge	(13)																
Income Tax Benefit (Provision)	1	(13)	-	-						(1,575)	(2,255)	(2,454)	(2,979)	25,922	39,049	56,421	78,711
<b>Tax Rate</b>					<b>0%</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>(4,312)</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>77,766</b>	<b>105,576</b>	<b>131,649</b>	<b>167,262</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>(0.04)</b>	<b>(0.17)</b>	<b>(0.12)</b>	<b>(0.11)</b>	<b>(0.10)</b>	<b>(0.10)</b>	<b>0.65</b>	<b>0.88</b>	<b>1.10</b>	<b>1.39</b>
GAAP EPS (dil)	(2.61)	(1.73)	(0.52)	(0.15)	(0.06)	(0.04)	(0.04)	(0.04)	(0.15)	(0.12)	(0.10)	(0.09)	(0.09)	0.54	0.71	0.85	1.04
Wgtd Avg Shrs (Bas) - '000s	4,058	7,986	30,351	82,807	102,634	116,411	116,527	116,644	113,054	116,936	117,404	117,875	118,347	118,821	119,297	119,775	120,255
Wgtd Avg Shrs (Dil) - '000s	4,058	7,986	47,643	110,550	102,634	116,411	117,575	118,751	113,843	121,749	126,693	131,837	137,190	142,761	148,557	154,590	160,866

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.

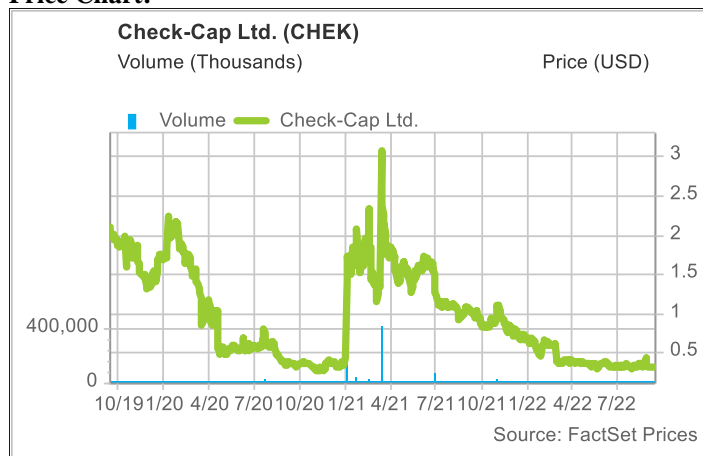
**Investment Risk.** Check-Cap is a small capital company, which can translate into high volatility and risk for investors. The company has no revenues and is dependent on the clinical progress of the device.

**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

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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 15-Sep-22

	<b>Company Coverage</b>		<b>Investment Banking</b>	
<b>Ratings Distribution</b>	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	27	90%	4	15%
Market Perform (Neutral)	2	7%	0	0%
Market Underperform (Sell)	1	3%	0	0%
<b>Total</b>	<b>30</b>	<b>100%</b>	<b>4</b>	<b>13%</b>

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