

INSTITUTIONAL RESEARCH Medical Devices RATING CHANGE REPORT

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Check-Cap (NASDAQ/CHEK)

Raising to Buy - U.S. Phase 3 Pivotal Trial Set to Begin

Check-Cap announced an agreement with regulators to begin the amended pivotal trial. The company hopes to start the study by March/April time frame. The study is designed in two parts. The first part is designed to enable further calibration of the system for the average at-risk U.S. population. The second part will include a statistically powered, randomized study that will compare C-Scan's performance to traditional colonoscopy.

Investment Highlights

Check-Cap now has plenty of cash and has made progress in Europe and the U.S. We are hopeful that the start of the U.S. pivotal trial can signal a recovery for the stock. Our fair-value calculations, for the moment, still suggest a \$1.00 target. Given the fall in the stock price to \$0.60 and the cash on the balance sheet (approx. \$57M), which equals the company's market capitalization, or an Enterprise value of zero, we see a more favorable risk-reward ratio. We have always believed in the product, and that has not changed. Our downgrade last year was driven by dilution concerns. Those concerns are now behind us. As a result, we upgrade the stock from Neutral to Buy and maintain our \$1.0 price target.

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.

Check-Cap raised Capital Last Year- Deal Terms: Check-Cap raised approximately \$32M last year plus \$19M in Warrants. The company now has plenty of cash, \$57M equal to its market capitalization.

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 212M (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 suggest a fair value of \$1.00

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

February 7, 2022

Jason Kolbert Senior Analyst jkolbert@dawsonjames.com



Source: Check-Cap		
Stock Data		
52-Week Range	\$0.43 -	\$4.49
Shares Outstanding (mil.)		96.4
Market Capitalization (mil	.)	\$58
Enterprise Value (mil.)		\$1
Debt to Capital		0%
Book Value/Share		\$0.53
Price/Book		1.3
Average Three Months Tra	ading Volume (K)	2,426
Insider Ownership		1.9%
Institutional Ownership		2.2%
Short interest (mil.)		5.3%
Dividend / Yield		\$0.00/0.0%





Exhibit 1. U.S. Model

Capsule Endoscopy - US	2021	E 2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Colorectal Cancer Screenings	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
%Not screened or Not Current (34%)	39,157,488	39,431,590	39,707,611	39,985,565	40,265,464	40,547,322	40,831,153	41,116,971	41,404,790	41,694,624
Market penetration	0.00%	þ			0.01%	0.02%	0.10%	0.20%	0.50%	1.00%
Total addressable patients				-	4,027	8,109	40,831	82,234	207,024	416,946
Patients with insurance	85%	s 85%	85%	85%	85%	85%	85%	85%	85%	85%
Total eligible patients	-	-	-	-	3,423	6,893	34,706	69,899	175,970	354,404
Tests per patient	1	1	1	1	1	1	1	1	1	1
Total tests needed	-	-	-	-	3,423	6,893	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%
Sales (\$000)	\$ -	\$ -	\$-	\$-	\$ 2,752	\$ 5,598	\$ 28,467	\$ 57,906	\$ 147,235	\$ 299,497
Risk adjustment	70%	5 70%	70%	70%	70%	70%	70%	70%	70%	70%
US Revenue (\$000)	\$-	\$-	\$-	\$ -	\$ 826	\$ 1,679	\$ 8,540	\$ 17,372	\$ 44,171	\$ 89,849

Source: Dawson James

Exhibit 2. E.U. Model

Capsule Endoscopy - EU		2021E	2022E		2023E	20	24E	2025E		2026E		2027E		2028E		2029E		2030E
Colorectal Cancer Screenings		57,859,662	58,264,680		58,672,533	59,083,2	40	59,496,823	5	9,913,301	60	,332,694	6	60,755,023	(61,180,308	6	1,608,570
% Not screened or Not Current (34%)		57,859,662	58,264,680		58,672,533	59,083,2	40	59,496,823	5	9,913,301	60	,332,694	6	60,755,023	(61,180,308	6	1,608,570
Market penetration					0.00%	0.0	0%	0.01%		0.50%		1.00%		1.30%		1.50%		1.70%
Total addressable patients	_	-	-	_	-			5,950	_	299,567		603,327	_	789,815	_	917,705	_	1,047,346
Patients with insurance	٢.	85%	85%		85%	8	5%	85%		85%		85%		85%		85%		85%
Total eligible patients		-	-		-			5,057		254,632		512,828		671,343		780,049		890,244
Tests per patient		1	1		1		1	1		1		1		1		1		1
Total tests needed		-	-		-			5,057		254,632		512,828		671,343		780,049		890,244
Cost per test	\$	541	\$ 552	\$	563	\$ 5	74	\$ 586	\$	586	\$	586	\$	586	\$	586	\$	586
Increase in price		2%	2%	_	2%		2%	2%		0%		0%		0%		0%		0%
Sales (\$000)	\$	- 1	\$-	\$		\$		\$ 2,963	\$	149,171	\$	300,430	\$	393,293	\$	456,976	\$	521,531
Risk adjustment	_	50%	50%		50%		0%	50%	_	50%		50%	_	50%	_	50%	_	50%
EU Total Sales (\$000)	\$	1	\$-	\$		\$		\$ 1,481	\$	74,585	\$	150,215	\$	196,646	\$	228,488	\$	260,766
Royalty rate		100%	100%		100%	10	0%	100%		100%		100%		100%		100%		100%
EU Revenue (\$000)	\$	-	\$-	\$	- :	\$		\$ 1,481	\$	74,585	\$	150,215	\$	196,646	\$	228,488	\$	260,766
Total Revenue (\$000)	\$	-	\$-	\$		\$		\$ 2,307	\$	76,265	\$	158,755	\$	214,018	\$	272,659	\$	350,615

Source: Dawson James



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). We assume additional capital raises (dilution) in our final projected fully diluted share count of 134M (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 suggest fair value at \$1.00

Exhibit 3. Free Cash Flow to the Firm

Average \$	
Price Target \$	1
Year	2022

DCF Valuation Using FCF (mln):													
units ('000)		2019A	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT		(13,836)	(13,846)	(13,520)	(13,070)	(12,508)	(12,039)	(9,926)	45,139	106,581	147,581	191,090	249,060
Tax Rate		0%	0%	0%	5%	10%	15%	17%	20%	25%	27%	30%	32%
EBIT(1-t)		(13,836)	(13,846)	(13,520)	(12,417)	(11,257)	(10,233)	(8,238)	36,111	79,936	107,734	133,763	169,361
CapEx		(167)	(203)	(247)	(300)	(365)	(443)	(539)	(655)	(796)	(967)	(1,176)	(1,429)
Depreciation		115	58	59	61	63	65	67	69	71	73	75	78
Change in NWC													
FCF		(13,888)	(13,991)	(13,707)	(12,656)	(11,559)	(10,611)	(8,710)	35,525	79,211	106,840	132,662	168,009
PV of FCF		(30,512)	(23,645)	(17,819)	(12,656)	(8,891)	(6,279)	(3,965)	12,438	21,334	22,135	21,142	20,596
Discount Rate	30%												
Long Term Growth Rate	1%												
Terminal Cash Flow	585,136												
Terminal Value YE2030	71,732												
NPV	137,586												
NPV-Debt	142												
Shares out (thousands)	134,025	2030E											
NPV Per Share	\$ 1.03												

Source: Dawson James

Exhibit 4. Discounted EPS

Current Year	2022			Discount F	Rate and Earnir	ngs Multiple Va	aries, Year is	s Constant	
Year of EPS	2030					2030 E	PS		
Earnings Multiple	10		1.5	5%	10%	15%	20%	25%	30%
		Earnings							
Discount Factor	30%	Multiple	5	\$4.28	\$2.95	\$2.07	\$1.47	\$1.06 \$	0.77
Selected Year EPS	\$ 1.26		10	\$8.55	\$5.90	\$4.13	\$2.94	\$2.12 \$	1.55
NPV	\$ 1.55		15	\$12.83	\$8.84	\$6.20	\$4.41	\$3.18 \$	2.32
Source: Dawson James estimates			20	\$17.11	\$11.79	\$8.26	\$5.88	\$4.24 \$	3.10
			25	\$21.38	\$14.74	\$10.33	\$7.35	\$5.30 \$	3.87
			30	\$25.66	\$17.69	\$12.39	\$8.82	\$6.36 \$	4.65
			35	\$29.94	\$20.63	\$14.46	\$10.29	\$7.42 \$	5.42
			40	\$34.21	\$23.58	\$16.52	\$11.76	\$8.48 \$	6.20

Exhibit 5. Sum of the Parts

Check-Cap	LT Gr	Discount Rate	Yrs. to Mkt Peak	% Success	Peak Sales MM's	Term Val
Imaging Capsule - US	1%	30%	7	30%	\$299	\$1,033
NPV						\$0.17
Imaging Capsule - EU	1%	30%	5	50%	\$261	\$899
NPV						\$0.41
Net Margin						45%
MM Shrs OS (2030E)						134
Total						\$1

Source: Dawson James



Exhibit 1. Income Statement

Check-Cap: Income Statement (\$000)																													
.: YE December 31	2018A	2019A	2020A	2021E	1Q22E	2Q22E	3Q22E	4Q22E	2022E	1Q23E	2Q23E	3Q23E	4Q23E	2023E	1Q24E	2Q24E	3Q24E	4Q24E	2024E	1Q25E	2Q25E	3Q25E	4Q25E	2025E	2026E	2027E	2028E	2029E	2030E
Product sales																													
Imaging capsule EU	•	-	-		-	-	-	-	-	-	-		-	-	-	-	-		-	356	341	385	400	1,481	74,585	150,215	196,646		260,766
Imaging capsule US	-	-	-	-		-	-	-			-	-	-	-	-	-	-	-	-	198	190	215	223	826	1,679	8,540	17,372	44,171	89,849
Total Product Sales	-	-	-	-	-			-		-	-	-	-	-	-	-		-	-	554	531	600	623	2,307	76,265	158,755	214,018	272,659	350,615
Expenses																													
Cost of Goods Sold			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	138	133	150	156	577	19,066	39,689	53,505	68,165	87,654
%COGS			0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%
Research and Development	7,618	10,474	10,008	9,007	1,946	1,864	2,108	2,189	8,106	1,751	1,678	1,897	1,970	7,296	1,576	1,510	1,707	1,773	6,566	1,418	1,359	1,537	1,596	5,910	5,969	6,028	6,089	6,150	6,211
%R&D																													
General and Administrative	3,445	3,595	3.924	4.513	1,191	1.142	1.291	1.340	4.964	1.251	1,199	1.355	1,407	5.212	1.313	1.259	1.423	1,478	5.473	1.379	1.322	1.494	1.551	5,746	6.091	6.457	6.844	7.255	7.690
%SG&A	0,110	0,000	-,	.,	.,	.,	.,	.,	.,	.,== .	.,	.,	.,	-,	.,	.,	.,	.,	-,	.,	.,	.,	.,	-,	-,	-,	-,	.,	.,
Total expenses	11.063	14.069	13,932	13.520	3,137	3.006	3,398	3.529	13.070	3.002	2.877	3.252	3.377	12,508	2.889	2.769	3,130	3.251	12.039	2.936	2.814	3,180	3,303	12.233	31,126	52,174	66.437	81,569	101,555
Operating Income (Loss)	(11.063)	(14.069)	(13,932)	(13.520)	(3,137)	(3.006)	(3.398)	(3.529)	(13,070)	(3.002)	(2.877)	(3.252)	(3,377)	(12,508)	(2.889)	(2.769)	(3.130)	(3,251)	(12.039)	(2.382)	(2.283)	(2.581)	(2.680)	(9.926)	45,139	106.581	147.581		
	(,)	(,,	((,	(0,101)	(0,000)	(0,000)	(0,020)	(,)	(0,002)	(=,)	(0,202)	(0,011)	((2,000)	(=))	(0,100)	(0,201)	(,,	(=)00=)	(=,===)	(=,== :)	(,)	(0,020)			,	,	
Finance income	473	233	86																										
Finance expenses																													
Total other income	473	233	86	-		-		-				-	-	-	-	-		.	-	-	-			-	-	-	-	-	-
Pretax Income	(10,590)	(13,836)	(13.846)	(13,520)	(3.137)	(3.006)	(3,398)	(3,529)	(13.070)	(3,002)	(2,877)	(3,252)	(3,377)	(12,508)	(2.889)	(2.769)	(3,130)	(3,251)	(12,039)	(2.382)	(2.283)	(2.581)	(2.680)	(9,926)	45,139	106,581	147.581	191.090	249,060
change in fair value of cash flow hedge	(13)						(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			()))										() -)									
Income Tax Benefit (Provision)	1	(13)	·	·	(157)	(150)	(170)	(176)	(654)	(300)	(288)	(325)	(338)	(1,251)	(433)	(415)	(470)	(488)	(1.806)	(405)	(388)	(439)	(456)	(1.687)	9.028	26,645	39.847	57.327	79.699
Tax Rate					5%	5%	5%	5%	5%	10%	10%	10%	10%	10%	15%	15%	15%	15%	15%	17%	17%	17%	17%	17%	20%	25%	27%	30%	32%
GAAP Net Income (loss)	(10.602)	(13.823)	(13.846)	(13.520)	(2.980)	(2.856)	(3.228)	(3.353)	(12,417)	(2.702)	(2.589)	(2.927)	(3.039)	(11,257)	(2,456)	(2.354)	(2.661)	(2.763)	(10.233)	(1.977)	(1.895)	(2.142)	(2.224)	(8,238)	36,111	79.936	107 734	133,763	169 361
	(10,002)	(10,020)	(10,040)	(10,020)	(2,000)	(2,000)	(0,220)	(0,000)	(12,511)	(2,102)	(2,000)	(2,521)	(0,000)	(11,207)	(2,400)	(2,004)	(2,001)	(2,700)	(10,200)	(1,577)	(1,000)	(2,142)	(2,224)	(0,200)	00,111	10,000	101,104	100,100	100,001
GAAP-EPS	(2.61)	(1.73)	(0.63)	(0.17)	(0.03)	(0.03)	(0.03)	(0.03)	(0.13)	(0.03)	(0.03)	(0.03)	(0.03)	(0.12)	(0.03)	(0.02)	(0.03)	(0.03)	(0.11)	(0.02)	(0.02)	(0.02)	(0.02)	(0.08)	0.37	0.81	1.09	1.35	1.71
GAAP EPS (dil)	(2.61)	(1.73)	(0.52)	(0.14)	(0.03)	(0.03)	(0.03)	(0.03)	(0.13)	(0.03)	(0.03)	(0.03)	(0.03)	(0.11)	(0.02)	(0.02)	(0.03)	(0.03)	(0.10)	(0.02)	(0.02)	(0.02)	(0.02)	(0.08)	0.32	0.67	0.87	1.04	1.26
Wgtd Avg Shrs (Bas) - '000s	4.058	7.986	30.351	82 580	96.027	96,123	96.219	96.315	96.171	96.411	96.508	96.604	96 701	96 556	96,798	96.894	96.991	97.088	96,943	97,185	97.283	97.380	97,477	97.331	97.721	98,113	98,506	98,900	99,297
Wgtd Avg Shrs (Dil) - '000s	4,058	7,986	47.643	110.550	96.027	96,987	97.957	98,936	97,477	99.926	100.925	101.934	102,954	101,435	103.983	105.023	106.073	107,134	105.553				111.484	109,839	114,299	118,940	123,770	128,795	134.025
rigid rag dina (bil) dada	4,030	7,500	-1,045		55,027	55,567	57,557	55,550	57,477	55,820	100,820	101,034	102,004	101,400	100,000	100,020	100,075	107,134	100,000	100,200	100,207	110,300		100,000		110,840	120,110	120,765	104,020

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.

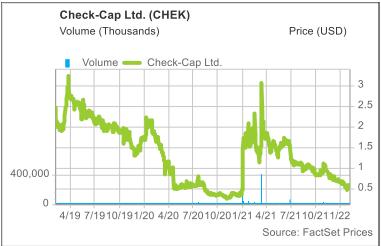


Companies mentioned in this report

PillCam is a product sold by Medtronic (MDT - Not Rated).

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

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Rating Definitions:

- 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.

The following chart reflects the range of current research report ratings for all companies followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

	Company Coverage		Investment Banking	
				% of
Ratings Distribution	# of Companies	% of Total	# of Companies	Totals
Market Outperform (Buy)	30	75%	6	20%
Market Perform (Neutral)	10	25%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	40	100%	6	15%

Current as of... 7-Feb-22

Analyst Certification:

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