

Check-Cap (NASDAQ/CHEK)

April 21, 2020

BUY: Raise Capital as COVID Potentially Pushes Timelines Out

Check-Cap announced a capital raise (selling 6.7M shares and equal number of warrants at \$0.60), bringing in approximately \$4M in cash; We adjust our model for both this raise and the fall in the stock price. The COVID Pandemic may push timelines out extending the need for additional operational cash. As a result, and with what in our opinion are conservative assumptions, our valuation falls from \$4.0 to \$2.0 principally as a result of what may be extended timelines triggering additional capital finance risk.

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Investment Highlights

Raise Capital as COVID Pushes Timelines. Check Cap ended the year with \$8M in cash and then raised another \$4.76M in February. We had hoped this would support the company through the start of the U.S. pivotal trial. COVID is changing everything and its now likely timelines get pushed out. As such, the company raised an additional \$4M. Our model has and continues to assume dilution. Given what may be extended timelines and the fall in the stock price, the effect on our model is a drop in the price target from \$4.00 to \$2.00 per share.

We Need Super-Pill. Just as Superman had X-ray vision, so does Check Cap's imaging device (we will call it "super-pill"). Super-pill is able to literally X-ray the colon, activating the sensors only when the device reaches the target area. The device uses a tiny X-ray source (with a harmless amount of radiation) and is "flushed" when eliminated from the body. No bowel prep, no diet changes, no invasive devices such as a scope, and no anesthesia are needed for a physician to see a detailed map of the entire colon and detect precancerous polyps – a paradigm shift. The data is then transmitted to a sensor, and the examination is completed. As such, we see super-pill creating an alternative option to traditional colonoscopy.

Colorectal cancer (CRC) is the third most common cancer diagnosed in people 50 years or older. There are more than 1M people living with colorectal cancer in the U.S., with 132,000 new incidents every year. CRC is highly preventable, and colorectal screening is the key to early detection of any precancerous polyps. Thus, CRC screening has a vast market upside as a result of the emphasis on early detection. Approximately 10M patients are screened in the U.S. every year, implying a \$2B market opportunity in the U.S. alone. Colonoscopy is the gold-standard screening and diagnostic procedure for CRC but also requires diet changes and intense bowel cleansing, which is followed by an invasive screening process. Thus, a non-invasive and easier screen modality for colorectal cancer is needed.

From optical colonoscopy to PillCam to the imaging capsule. Can Check-Cap lead to the next paradigm shift? In our opinion, Check-Cap's imaging capsule can revolutionize colon screening regimens. Though PillCam was once a breakthrough in the colon endoscopy space, it only serves as a complementary alternative for those who fail to complete a colonoscopy, and it still requires intense bowel cleansing prior to the screen. In addition, PillCam uses an encapsulated camera to snap pictures while traveling through the colon. Still, the camera may not be able to capture hidden polyps in the folded areas of the intestine and colon. Check-Cap's imaging capsule not only can provide the advantages of non-invasiveness with no bowel prep, but it also enables the visualization of the entire colon with uncompromised sensitivity and specificity.

Current Price	\$0.53		
Price Target	\$2.00		
Estimates	F2019A	F2020E	F2021E
Expenses (\$000s)	\$ 14,069	\$ 13,453	\$ 13,114
1Q March	\$ 3,164	\$ 3,229	\$ 3,147
2Q June	\$ 3,494	\$ 3,094	\$ 3,016
3Q September	\$ 3,564	\$ 3,498	\$ 3,410
4Q December	\$ 3,847	\$ 3,632	\$ 3,541
	F2019A	F2020E	F2021E
EPS (diluted)	\$ (1.73)	\$ (0.78)	\$ (0.26)
1Q March	\$ (0.44)	\$ (0.39)	\$ (0.06)
2Q June	\$ (0.41)	\$ (0.14)	\$ (0.06)
3Q September	\$ (0.42)	\$ (0.16)	\$ (0.07)
4Q December	\$ (0.46)	\$ (0.09)	\$ (0.07)
EBITDA/Share	(\$1.73)	(\$0.85)	(\$0.41)
EV/EBITDA (x)	0.0	0.0	0.0
Stock Data			
52-Week Range	\$0.44	-	\$2.80
Shares Outstanding (mil.)	11.0		
Market Capitalization (mil.)	\$6		
Enterprise Value (mil.)	\$6		
Debt to Capital	0%		
Book Value/Share	\$0.53		
Price/Book	2.3		
Average Three Months Trading Volume (K)	36		
Insider Ownership	0.7%		
Institutional Ownership	0.5%		
Short interest (mil.)	1.2%		
Dividend / Yield	\$0.00/0.0%		



What is the Approval Status? In Europe, the company announced positive final results from the post C.E. mark approval study of the C-Scan System. The study met its primary endpoint, achieving a sensitivity of 76% in patients with polyps ≥ 10 mm and specificity of 82% in all patients, compared to fecal immunochemical test (FIT) that achieved 29% sensitivity and 96% specificity. In addition, the C-Scan System detected all four patients (100%) with polyps ≥ 40 mm, while FIT detected only 1 of the four patients (25%) with polyps ≥ 40 mm. Overall, the C-Scan System achieved a sensitivity of 66% in all patients (including patients with polyps < 10 mm), while FIT achieved a sensitivity of 23% for the same population. In the U.S., a pilot study is underway. The study is a single-arm trial enrolling up to 45 subjects considered to be of average risk for polyps and colon cancer. The study plans to evaluate the safety, usability, and subject compliance of the C-Scan system. The study is being conducted at the NYU School of Medicine and Mayo Clinic and is expected to complete this year. Upon successful completion of the pilot study, and with the required capital, management plans to initiate (2020) a pivotal study in the U.S. We expect the study to be a multi-center, safety and performance trial. Other geographies such as Japan and China are being considered, subject to capital, and strategic partnerships.

Conclusion: Colorectal cancer is deadly, yet preventable with early detection. The arduous preparation, however, keeps many people from having the test done, making patient compliance a major challenge. An ingestible capsule with no prep could be paradigm-shifting and drive increased adoption in the \$2B colorectal screening market. Our analysis of the data suggests that super-pill is comparable in terms of detection.

Valuation. Our valuation is based on the assumed success of the E.U. launch of Check-Cap's imaging capsule, followed by a successful outcome for the U.S. registration study and commercial launch. We use a 30% probability of success for the EU and US 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 share count of 82M (2030) versus 4Q19 count of 8M* shares. We then apply these projections into our Free Cash Flow to the Firm or FCFE, 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.

* We note the raise in February and April have raised the share count.

Risk Factors: These include Clinical Risk, Partnership Risk, Investment and Financial Risk, Regulatory Risk, Market Share Risk, and Legal and Commercial Risks.

Modeling Assumptions:

1. Check-Cap's imaging capsule should begin to generate European sales in 2021. We expect that a U.S. registration trial will be initiated following a positive outcome for the current pilot study. We do not model in revenues in Israel, which could be up[side to our model.
2. We assume the price for the imaging capsule therapy is \$600 per use.
3. We assume modest single-digit market peak penetration in both the U.S. and European markets.
4. We use a highly conservative 30% discount rate in addition to a risk cut 30% in our E.U. and U.S. models, which feeds into our income statement. Three models, Free cash flow to the Firm (FCFF), Discounted EPS, and sum of the parts models, which are then averaged and equal-weighted.

Exhibit 1. Check-Cap Imaging Capsule Product Model (EU)

Capsule Endoscopy - US	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Colorectal Cancer Screenings	100,000,000	100,700,000	101,404,900	114,368,502	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%)	34,000,000	34,238,000	34,477,666	38,885,291	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%	0.00%	0.00%	-	0.01%	0.05%	0.10%	0.20%	0.50%	1.00%	2.00%	3.00%
Total addressable patients	-	-	-	-	-	-	3,971	19,993	40,265	81,095	204,156	411,170	828,096	1,250,839
Patients with insurance	-	-	85%	85%	85%	85%	85%	85%	85%	85%	85%	85%	85%	85%
Total eligible patients	-	-	-	-	-	-	3,375	16,994	34,226	68,930	173,532	349,494	703,881	1,063,213
Tests per patient	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Total tests needed	-	-	-	-	-	-	3,375	16,994	34,226	68,930	173,532	349,494	703,881	1,063,213
Cost per test	-	\$ 600	\$ 630	\$ 662	\$ 695	\$ 729	\$ 766	\$ 804	\$ 812	\$ 820	\$ 828	\$ 837	\$ 845	
Increase in price	-	5%	5%	5%	5%	5%	5%	5%	5%	1%	1%	1%	1%	
Sales (\$000)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 2,462	\$ 13,013	\$ 27,519	\$ 55,978	\$ 142,335	\$ 289,528	\$ 588,941	\$ 898,492
Risk adjustment	-	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%
US Revenue (\$000)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 738	\$ 3,904	\$ 8,256	\$ 16,793	\$ 42,700	\$ 86,859	\$ 176,682	\$ 269,548

Source: Dawson James

Exhibit 2. Check-Cap Imaging Capsule Product Model (US)

Capsule Endoscopy - EU	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Colorectal Cancer Screenings	46,889,626	47,217,853	47,548,378	57,457,460	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
% Not screened or Not Current (34%)	46,889,626	47,217,853	47,548,378	57,457,460	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
Market penetration	0.00%	0.00%	0.00%	0.00%	0.01%	0.50%	1.00%	1.30%	1.50%	1.70%	1.90%	2.10%	2.30%	2.50%
Total addressable patients	-	-	-	-	5,786	291,323	586,725	768,082	892,452	1,018,526	1,146,321	1,275,855	1,407,147	1,540,214
Patients with insurance	85%	85%	85%	85%	85%	85%	85%	85%	85%	85%	85%	85%	85%	85%
Total eligible patients	-	-	-	-	4,918	247,625	498,717	652,870	758,584	865,747	974,373	1,084,477	1,196,075	1,309,182
Tests per patient	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Total tests needed	-	-	-	-	4,918	247,625	498,717	652,870	758,584	865,747	974,373	1,084,477	1,196,075	1,309,182
Cost per test	\$ 500	\$ 510	\$ 520	\$ 531	\$ 541	\$ 552	\$ 563	\$ 574	\$ 586	\$ 586	\$ 586	\$ 586	\$ 586	\$ 586
Increase in price	-	2%	2%	2%	2%	2%	2%	2%	2%	0%	0%	0%	0%	0%
Sales (\$000)	\$ -	\$ -	\$ -	\$ -	\$ 2,662	\$ 136,699	\$ 280,818	\$ 374,971	\$ 444,401	\$ 507,180	\$ 570,817	\$ 635,319	\$ 700,696	\$ 766,958
Risk adjustment	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%
EU Total Sales (\$000)	\$ -	\$ -	\$ -	\$ -	\$ 799	\$ 41,010	\$ 84,245	\$ 112,491	\$ 133,320	\$ 152,154	\$ 171,245	\$ 190,596	\$ 210,209	\$ 230,087
Royalty rate	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
EU Revenue (\$000)	\$ -	\$ -	\$ -	\$ -	\$ 799	\$ 41,010	\$ 84,245	\$ 112,491	\$ 133,320	\$ 152,154	\$ 171,245	\$ 190,596	\$ 210,209	\$ 230,087

Source: Dawson James

Valuation: Our valuation is based on the assumed success of the E.U. launch of Check-Cap's imaging capsule, followed by a successful outcome for the U.S. registration study and commercial launch in the U.S. We use a 30% probability in our model that our sales goals can be achieved in Europe and approval/commercialization in the U.S. The 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 share count of 80M (2030) versus 4Q19 count of 8M shares. We then apply these projections into our Free Cash Flow to the Firm or FCF, 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.

Exhibit 3. FCFF Model

Average	\$	2
Price Target	\$	3
Year		2020

DCF Valuation Using FCF (mln):

units ('000)	2019A	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(13,836)	(13,453)	(12,316)	28,281	72,764	75,496	94,720	114,839	148,156	195,333	276,932	360,985
Tax Rate	0%	0%	0%	5%	10%	15%	17%	20%	25%	27%	30%	32%
EBIT(1-t)	(13,836)	(13,453)	(12,316)	26,867	65,487	64,172	78,617	91,871	111,117	142,593	193,853	245,470
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)	(13,598)	(12,503)	26,628	65,186	63,794	78,146	91,285	110,392	141,699	192,752	244,119
PV of FCF	(18,054)	(13,598)	(9,618)	15,756	29,670	22,336	21,047	18,912	17,593	17,371	18,176	17,708
Discount Rate	30%											
Long Term Growth Rate	1%											
Terminal Cash Flow	850,206											
Terminal Value YE2025	61,672											
NPV	217,026											
NPV-Debt	266											
Shares out (thousands)	82,379	2030E										
NPV Per Share	\$	3										

Source: Dawson James

Exhibit 4. Discounted EPS Model

Current Year	2020
Year of EPS	2030
Earnings Multiple	5
Discount Factor	30%
Selected Year EPS	\$ 2.98
NPV	\$ 1

Source: Dawson James estimates

		Discount Rate and Earnings Multiple Varies, Year is Constant						
		2030 EPS						
Earnings Multiple		1.1	5%	10%	15%	20%	25%	30%
5			\$9.15	\$5.74	\$3.68	\$2.41	\$1.60	\$ 1.08
10			\$18.29	\$11.49	\$7.37	\$4.81	\$3.20	\$ 2.16
15			\$27.44	\$17.23	\$11.05	\$7.22	\$4.80	\$ 3.24
20			\$36.59	\$22.98	\$14.73	\$9.63	\$6.40	\$ 4.32
25			\$45.73	\$28.72	\$18.41	\$12.03	\$8.00	\$ 5.40
30			\$54.88	\$34.46	\$22.10	\$14.44	\$9.60	\$ 6.48
35			\$64.03	\$40.21	\$25.78	\$16.84	\$11.20	\$ 7.57
40			\$73.17	\$45.95	\$29.46	\$19.25	\$12.80	\$ 8.65

Source: Dawson James

Exhibit 5. Sum of the Parts Model

Check-Cap	LT Gr	Discount Rate	Yrs. to Mkt Peak	% Success	Peak Sales MMs	Term Val
Imaging Capsule - US	1%	30%	5	30%	\$898	\$3,098
NPV						\$1.37
Imaging Capsule - EU	1%	30%	3	30%	\$230	\$793
NPV						\$0.59
Net Margin						45%
MM Shrs OS (2030E)						82
Total						\$2

Source: Dawson James

Exhibit 6. Income Statement

Check-Cap: Income Statement (\$000)																	
: YE December 31	2018A	2019A	1Q20E	2Q20E	3Q20E	4Q20E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Product sales																	
Imaging capsule EU	-	-	-	-	-	-	-	799	41,010	84,245	112,491	133,320	152,154	171,245	190,596	210,209	230,087
Imaging capsule US	-	-	-	-	-	-	-	-	-	738	3,904	8,256	16,793	42,700	86,859	176,682	269,548
Total Product Sales	-	-	-	-	-	-	-	799	41,010	84,984	116,395	141,576	168,948	213,945	277,454	386,891	499,635
Expenses																	
Cost of Goods Sold			0	0	0	0	0	0	0	0	29,099	35,394	42,237	53,486	69,364	96,723	124,909
			%COGS														
Research and Development	7,618	10,474	2,262	2,168	2,451	2,545	9,427	8,484	7,636	6,872	6,185	5,566	5,622	5,678	5,735	5,792	5,850
			%R&D														
General and Administrative	3,445	3,595	966	926	1,047	1,087	4,026	4,630	5,093	5,348	5,615	5,896	6,250	6,625	7,023	7,444	7,891
			%SG&A														
Total expenses	11,063	14,069	3,229	3,094	3,498	3,632	13,453	13,114	12,729	12,220	40,899	46,857	54,109	65,790	82,121	109,959	138,649
Operating Income (Loss)	(11,063)	(14,069)	(3,229)	(3,094)	(3,498)	(3,632)	(13,453)	(12,316)	28,281	72,764	75,496	94,720	114,839	148,156	195,333	276,932	360,985
Finance income	473	233															
Finance expenses	-	-															
Total other income	473	233	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pretax Income	(10,590)	(13,836)	(3,229)	(3,094)	(3,498)	(3,632)	(13,453)	(12,316)	28,281	72,764	75,496	94,720	114,839	148,156	195,333	276,932	360,985
change in fair value of cash flow hedge	(13)																
Income Tax Benefit (Provision)	1	(13)	-	-	-	-	-	-	1,414	7,276	15,689	16,102	22,968	37,039	52,740	83,080	115,515
Tax Rate									5%	10%	15%	17%	20%	25%	27%	30%	32%
GAAP Net Income (loss)	(10,602)	(13,823)	(3,229)	(3,094)	(3,498)	(3,632)	(13,453)	(12,316)	26,867	65,487	59,807	78,617	91,871	111,117	142,593	193,853	245,470
GAAP-EPS	(2.61)	(1.73)	(0.39)	(0.21)	(0.23)	(0.14)	(0.97)	(0.41)	0.89	1.62	2.19	1.93	2.25	2.71	3.46	4.69	5.91
GAAP EPS (dil)	(2.61)	(1.73)	(0.39)	(0.14)	(0.16)	(0.09)	(0.78)	(0.26)	0.54	1.05	0.92	1.16	1.31	1.52	1.87	2.45	2.98
Wgtd Avg Shrs (Bas) - '000s	4,058	7,986	8,346	15,021	15,036	25,051	15,863	30,121	30,242	40,378	40,540	40,702	40,865	41,029	41,193	41,358	41,524
Wgtd Avg Shrs (Dil) - '000s	4,058	7,986	8,346	21,630	21,846	42,065	23,472	48,202	50,159	62,347	64,879	67,513	70,254	73,107	76,075	79,164	82,379

Source: Dawson James

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 claiming 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

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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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Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	22	92%	3	14%
Market Perform (Neutral)	2	8%	1	50%
Market Underperform (Sell)	0	0%	0	0%
Total	24	100%	4	17%

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