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Check Cap (NASDAQ/CHEK)

BUY: Capital Raised, Catalysts Ahead

Check Cap reported fourth quarter 2019 results ending the period with \$8M in cash and then raising an additional \$4.76M in February in a private placement. The U.S. pivotal trial, pending FDA approval, could begin this year.

Investment Highlights

2019 Full Year Results. Check Cap ended the year with \$8M in cash and then raised another \$4.76M, which should support the company through the start of the U.S. pivotal trial.

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 huge 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, but 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.

March 9, 2020

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 Healthcare Research
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Current Price **\$1.41**
 Price Target **\$4.00**

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)	\$ (0.40)	\$ (0.29)
1Q March	\$ (0.44)	\$ (0.10)	\$ (0.07)
2Q June	\$ (0.41)	\$ (0.09)	\$ (0.07)
3Q September	\$ (0.42)	\$ (0.10)	\$ (0.08)
4Q December	\$ (0.46)	\$ (0.11)	\$ (0.08)

EBITDA/Share	(\$1.73)	(\$0.73)	(\$0.50)
EV/EBITDA (x)	0.0	0.0	0.0

Stock Data		
52-Week Range	\$1.28	\$3.50
Shares Outstanding (mil.)	8.3	
Market Capitalization (mil.)	\$12	
Enterprise Value (mil.)	\$12	
Debt to Capital	0%	
Book Value/Share	\$0.53	
Price/Book	0.9	
Average Three Months Trading Volume (K)	18	
Insider Ownership	1.6%	
Institutional Ownership	1.1%	
Short interest (mil.)	4.7%	
Dividend / Yield	\$0.00/0.0%	



Please find Important Disclosures beginning on Page 7.

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 in the U.S. We use varying success probabilities for each geography (Europe and the U.S.), ranging from just 30% (U.S.) to 50% (Europe), that our sales goals can be achieved (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 71M (2030) versus 4Q19 count of 8M* shares. We then apply these projections into 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.

* We note the raise in February 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[s]ide to our model.
2. We assume the price for the imaging capsule therapy is \$600 peruse.
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 (50%) in our E.U. and 70% in our 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 - 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%	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	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
EU Total Sales (\$000)	\$ -	\$ -	\$ -	\$ -	\$ 1,331	\$ 68,349	\$ 140,409	\$ 187,486	\$ 222,201	\$ 253,590	\$ 285,408	\$ 317,659	\$ 350,348	\$ 383,479
Royalty rate	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
EU Revenue (\$000)	\$ -	\$ -	\$ -	\$ -	\$ 1,331	\$ 68,349	\$ 140,409	\$ 187,486	\$ 222,201	\$ 253,590	\$ 285,408	\$ 317,659	\$ 350,348	\$ 383,479

Source: Dawson James

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

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
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	\$ 845
Increase in price	-	5%	5%	5%	5%	5%	5%	5%	5%	1%	1%	1%	1%	1%
Sales (\$000)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 2,462	\$ 13,013	\$ 27,519	\$ 55,978	\$ 142,335	\$ 289,528	\$ 588,941	\$ 898,492	\$ 898,492
Risk adjustment	70%	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

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 varying success probabilities for each geography (Europe and the U.S.), ranging from just 30% (U.S.) to 50% (Europe), that our sales goals can be achieved (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 70M (2030) versus 3Q19 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. FCF Model

Average	\$	4
Price Target	\$	5
Year		2020

DCF Valuation Using FCF (mln):

units ('000)	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(13,572)	(13,000)	(11,367)	56,002	129,277	132,063	161,675	191,216	234,084	290,942	382,354	476,352
Tax Rate	0%	0%	0%	0%	10%	15%	17%	20%	25%	27%	30%	32%
EBIT(1-t)	(13,572)	(13,000)	(11,367)	56,002	116,349	112,253	134,190	152,973	175,563	212,388	267,648	323,920
CapEx	(144)	(175)	(213)	(259)	(315)	(382)	(465)	(565)	(687)	(835)	(1,014)	(1,233)
Depreciation	84	58	59	61	63	65	67	69	71	73	75	78
Change in NWC												
FCF	(13,632)	(13,117)	(11,521)	55,805	116,098	111,936	133,792	152,477	174,947	211,626	266,709	322,764
PV of FCF	(17,722)	(13,117)	(8,862)	33,020	52,844	39,192	36,034	31,590	27,881	25,943	25,151	23,413
Discount Rate	30%											
Long Term Growth Rate	1%											
Terminal Cash Flow	1,124,110											
Terminal Value YE2025	81,541											
NPV	354,628											
NPV-Debt	266											
Shares out (thousands)	70,958											2030E
NPV Per Share	\$ 5											

Source: Dawson James

Exhibit 4. Discounted EPS Model

Current Year	2020
Year of EPS	2030
Earnings Multiple	10
Discount Factor	30%
Selected Year EPS	\$ 4.56
NPV	\$ 3

Source: Dawson James estimates

Discount Rate and Earnings Multiple Varies, Year is Constant							
2030 EPS							
Earnings Multiple	3.3	5%	10%	15%	20%	25%	30%
5		\$14.01	\$8.80	\$5.64	\$3.69	\$2.45	\$ 1.66
10		\$28.03	\$17.60	\$11.28	\$7.37	\$4.90	\$ 3.31
15		\$42.04	\$26.40	\$16.93	\$11.06	\$7.35	\$ 4.97
20		\$56.05	\$35.20	\$22.57	\$14.75	\$9.80	\$ 6.62
25		\$70.06	\$44.00	\$28.21	\$18.43	\$12.25	\$ 8.28
30		\$84.08	\$52.80	\$33.85	\$22.12	\$14.70	\$ 9.93
35		\$98.09	\$61.60	\$39.49	\$25.80	\$17.16	\$ 11.59
40		\$112.10	\$70.40	\$45.14	\$29.49	\$19.61	\$ 13.25

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						\$1.59
Imaging Capsule - EU	1%	30%	3	50%	\$383	\$1,322
NPV						\$1.91
Net Margin						45%
MM Shrs OS (2030E)						71
Total						\$3

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	-	-	-	-	-	-	-	1,331	68,349	140,409	187,486	222,201	253,590	285,408	317,659	350,348	383,479
Imaging capsule US	-	-	-	-	-	-	-	-	-	738	3,904	8,256	16,793	42,700	86,859	176,682	269,548
Total Product Sales	-	-	-	-	-	-	-	1,331	68,349	141,147	191,390	230,456	270,384	328,109	404,518	527,031	653,026
Expenses																	
Cost of Goods Sold			0	0	0	0	0	0	0	0	47,847	57,614	67,596	82,027	101,129	131,758	163,257
			0%	0%	0%	0%	0%	0%	0%	0%	25%	25%	25%	25%	25%	25%	25%
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	59,648	69,077	79,468	94,330	113,887	144,994	176,997
Operating Income (Loss)	(11,063)	(14,069)	(3,229)	(3,094)	(3,498)	(3,632)	(13,453)	(11,783)	55,621	128,927	131,742	161,380	190,916	233,778	290,631	382,037	476,029
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)	(11,783)	55,621	128,927	131,742	161,380	190,916	233,778	290,631	382,037	476,029
change in fair value of cash flow hedge	(13)																
Income Tax Benefit (Provision)	1	(13)	-	-	-	-	-	-	2,781	12,893	26,938	27,435	38,183	58,445	78,470	114,611	152,329
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)	(11,783)	52,840	116,035	104,804	133,945	152,733	175,334	212,161	267,426	323,700
GAAP-EPS	(2.61)	(1.73)	(0.18)	(0.17)	(0.19)	(0.20)	(0.73)	(0.50)	2.24	3.45	4.52	3.95	4.48	5.13	6.18	7.76	9.35
GAAP EPS (dil)	(2.61)	(1.73)	(0.10)	(0.09)	(0.10)	(0.11)	(0.40)	(0.29)	1.26	2.16	1.87	2.30	2.52	2.78	3.23	3.92	4.55
Wgtd Avg Shrs (Bas) - '000s	4,058	7,986	18,346	18,365	18,383	18,401	18,374	23,455	23,549	33,658	33,793	33,929	34,064	34,201	34,338	34,475	34,614
Wgtd Avg Shrs (Dil) - '000s	4,058	7,986	33,346	33,680	34,017	34,357	33,850	40,300	41,936	53,790	55,974	58,247	60,612	63,073	65,634	68,299	71,072

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 Isreal, 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.

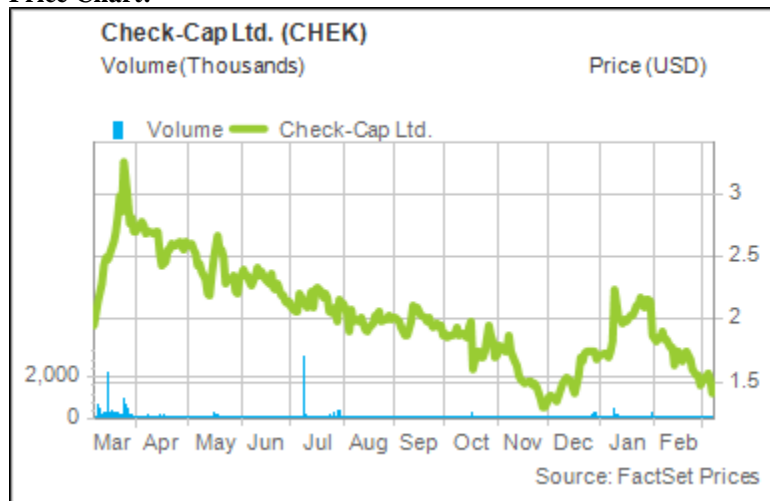
Regulatory Risk. Check-Cap, even with good clinical data, could face extensive delays and other regulatory setbacks.

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

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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.

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.

Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	22	85%	3	14%
Market Perform (Neutral)	4	15%	1	25%
Market Underperform (Sell)	0	0%	0	0%
Total	26	100%	4	15%

Analyst Certification:

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