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Check Cap (NASDAQ/CHEK)

BUY: A "Super-Pill" Complete with X-ray Vision

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. The data is then transmitted to a sensor, and the examination is complete. As such, we see the device as making a virtual colonoscopy available to all of us who shun the arduous preparation associated with traditional colonoscopy, and succeeding where PillCam (which requires a similar prep. to a colonoscopy) has not become popular.

Investment Highlights

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 a 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 US, 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 US every year implying a \$2B market opportunity in the US 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 colonendoscope 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.

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Current Price \$1.39
Price Target \$4.00

Estimates	F2019E	F2020E	F2021E
Expenses (\$000s)	\$ 13,572	\$ 13,000	\$ 12,698
1Q March	\$ 3,164	\$ 3,120	\$ 3,048
2Q June	\$ 3,494	\$ 2,990	\$ 2,921
3Q September	\$ 3,564	\$ 3,380	\$ 3,302
4Q December	\$ 3,350	\$ 3,510	\$ 3,429
	F2019E	F2020E	F2021E
EPS (diluted)	\$ (1.68)	\$ (0.38)	\$ (0.28)
1Q March	\$ (0.44)	\$ (0.09)	\$ (0.07)
2Q June	\$ (0.41)	\$ (0.09)	\$ (0.07)
3Q September	\$ (0.42)	\$ (0.10)	\$ (0.07)
4Q December	\$ (0.41)	\$ (0.10)	\$ (0.08)

EBITDA/Share	(\$1.70)	(\$0.71)	(\$0.49)
EV/EBITDA (x)	0.0	0.0	0.0

Stock Data		
52-Week Range	\$1.28	- \$4.20
Shares Outstanding (mil.)	8.3	
Market Capitalization (mil.)	\$11	
Enterprise Value (mil.)	\$11	
Debt to Capital	0%	
Book Value/Share	\$0.53	
Price/Book	0.9	
Average Three Months Trading Volume (K)	107	
Insider Ownership	2.0%	
Institutional Ownership	1.4%	
Short interest (mil.)	7.1%	
Dividend / Yield	\$0.00/0.0%	



What is the Approval Status? In Europe, the company announced positive final results from the post CE 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 EU 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 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.

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

Company Overview

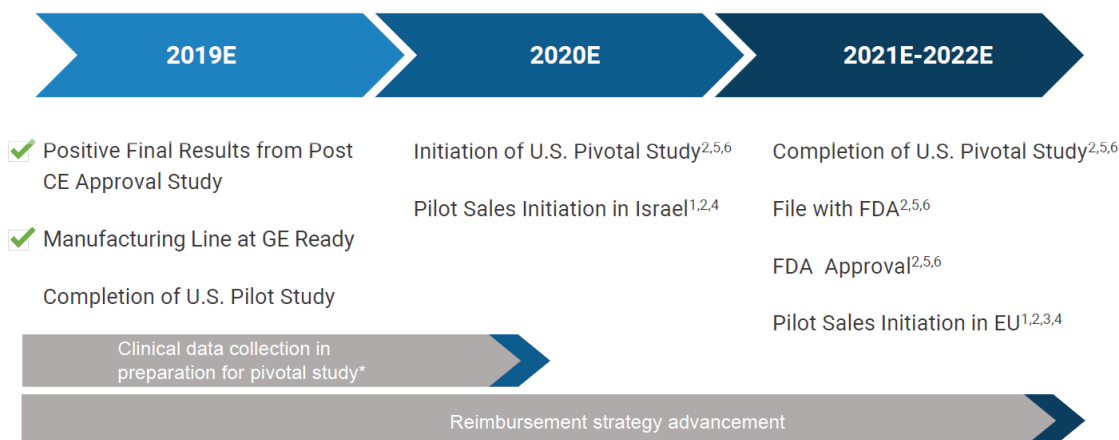
Check-Cap LTD is an emerging medical diagnostics company focused on the development and commercialization of an ingestible imaging capsule that scans the intestinal wall of the colon for the detection of precancerous polyps and colorectal cancer (CRC). Check-Cap's imaging capsule is designed as the first structural CRC screening solution that does not require any cleansing of the colon.

The company's activities are focused on developing a capsule endoscopy that utilizes low-dose X-rays. Similar to other capsule endoscopy solutions on the market, Check-Cap is developing a non-invasive CRC imaging solution, but with the proprietary technology that intends to provide a 360-degree, angular scan (compared to approximately a 180-degree scan offered by optic-based capsules) that does not require bowel cleansing. The development of the capsule is concurrent with that of an external tracker, as well as data-analysis software. The company's strategy is to extend the underlying science and clinical data to reach commercialization.

The Company announced positive final results from a post-CE approval study evaluating the clinical performance and safety of the C-Scan system. The study was designed to determine the performance characteristics of Check-Cap's capsule-based screening test, the C-Scan system, for detecting pre-cancerous polyps compared with the fecal immunochemical test (FIT), a commonly used non-invasive colorectal cancer screening test; in each case using colonoscopy as the reference method. The product was approved (CE mark) in 2018 (Jan. 9, 2018) in Europe. We also note it was approved in Israel too. A small U.S. pilot study is now 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 will evaluate the safety, usability, and subject compliance of the C-Scan system. Upon completion of the study and the availability of the required capital, the plan is to initiate (2020) a U.S. multi-center pivotal study. The company hopes to submit a direct de novo reclassification petition, (if all goes well, in 2021), for initial FDA approval for the marketing of the C-Scan system. Direct de novo reclassification typically takes at least nine to twelve months from filing to clearance. If the FDA determines that the C-Scan system is not a candidate for de novo reclassification, it will require approval of the device for market through the PMA process. The PMA pathway is much more costly and uncertain than the 510(k) clearance process or de novo reclassification, and generally takes at least 12 to 18 months, or even longer, from the time the application is filed with FDA to ultimate approval.

Exhibit 1. Catalysts

Near-Term Major Milestones



* Includes potential larger-scale pre-pivotal study in subjects considered to be average risk
 1. Pending strategic partnership
 2. Pending sufficient capital
 3. Pending additional regulatory approval as may be required
 4. Pending manufacturing cost reduction
 5. Assuming de novo classification, no PMA and no additional clinical studies required
 6. Pending success in clinical studies and data collection

Source: Check-Cap

Bull Case. Colorectal cancer is one of the most prevalent cancers in the world, representing a \$2B market in the U.S., yet it's highly preventable through early detection via colonoscopy, the gold-standard diagnostic. However, colonoscopy requires prerequisite changes in diet and uncomfortable bowel prep, which is followed by an invasive screening process. These factors contribute to patients avoiding testing, resulting in many cases of cancer that otherwise would have been prevented. Check-Cap's ingestible imaging capsule is a non-invasive alternative to colonoscopy that also requires no bowel prep or dietary changes. The imaging capsule is currently approved in Europe, with a U.S. pilot study that should lead to a registrational pivotal study in 2020. The capsule should begin to be commercialized in Europe and Israel with the U.S. to follow by 2022. If successful, even modest market penetration represents significant revenues for the company.

Bear Case. Currently Check-Cap is gearing up to commercialize the product in Europe, but thus far resources are limited. Without a partner, or the needed capital, the launch is likely to be constrained. In the U.S. we are waiting for the outcome of the pilot study which is likely to be followed by a larger (more expensive) multi-centered pivotal study. Check-Cap could still be years away from a U.S. launch. The major market segment for the imaging capsule is in the U.S., which means an EU launch, though positive, will not drive revenues to the bottom line and value for investors. Check-Cap is also competing with similar non-invasive colorectal screening products on the market, such as PillCam, and may also be following a similar regulatory pathway in the U.S. (PillCam enrolled 884 patients in 16 sites for its phase 3 pivotal trial). These factors elongate the road to break even or being cash-flow positive. The imaging capsule is Check-Cap's only product; the EU commercialization and outcome of the U.S. pilot study are key events for the company.

Our Take. Patients' compliance to get a colonoscopy is poor and, consequently, has resulted in an increase in the number of cases of colorectal cancer reported each year. We believe Check-Cap's imaging capsule has the potential to be an alternative non-invasive colorectal cancer screening regimen. The image capsule, which has no major commercially available competitors, can provide a detailed map of the entire colon and detect precancerous polyps with no bowel prep, no diet changes, and no invasive tubes or anesthesia. Its competitor, PillCam, only works as a complementary detection of colon polyps in patients after an incomplete optical colonoscopy, and it requires the same or even more intense bowel cleansing. Additionally, Check-Cap's novel X-ray imaging mechanism, compared with PillCam's capsuled camera snapping pictures while traveling through the colon, is advantageous. Its low radiation can "see through - 360°" and detect polyps, overcoming PillCam's inability to penetrate the lining, and observe the cancerous growth that is unseen due to the highly folded nature of the human intestine and colon.

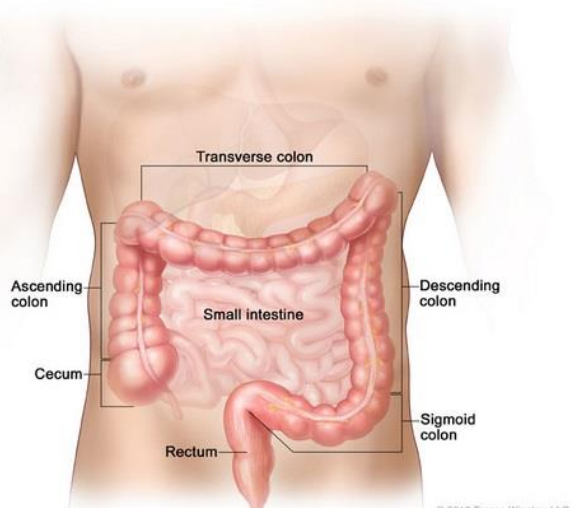
We believe this could translate into significant market uptake and return for investors, but it may take some time. So, the question is: What is the probability of success? The image capsule is the only product in development for the company, and, therefore, it makes the commercial launch in Europe and the outcome of the U.S. pilot study as key events to watch. Given the current market capitalization of the company and the fact that the product is approved in Europe, and is likely with time to be commercialized in the U.S., we see good value in the company today.

Check-Cap Financials. As of 3Q19, the company reported just over \$11M in cash or approximately one year of operating capital. We assume multiple capital raises and a 2030 out-year share count of 70M shares vs. 3Q19 of 8M shares.

Colorectal cancer (CRC) background.

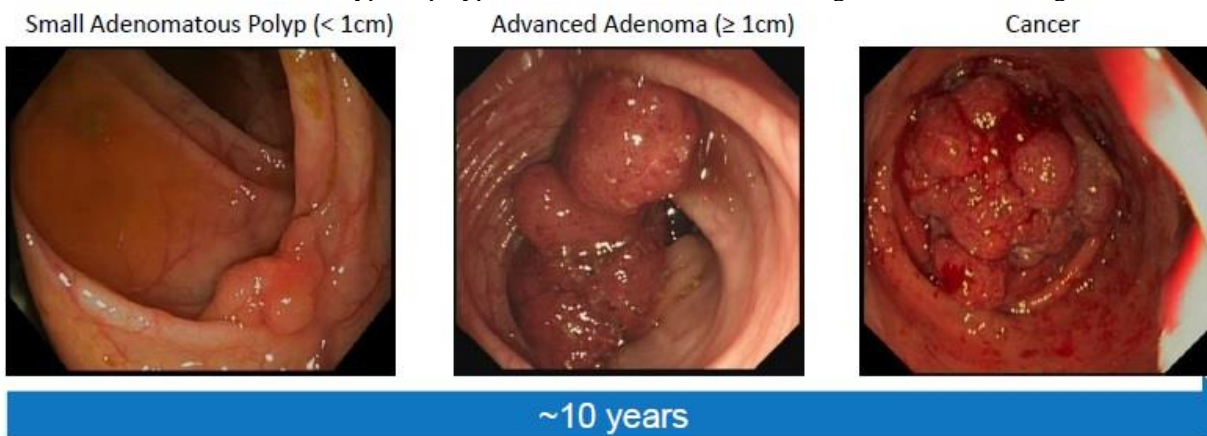
CRC is a disease in which abnormal cells in the colon or rectum divide uncontrollably, ultimately forming a malignant tumor. (The colon and rectum are parts of the body’s digestive system, which takes up nutrients from food and water, and stores solid waste until it passes out of the body.) CRC affects men and women of all racial and ethnic groups and is most often found in people 50 years old or older. According to statistics from the American Society of Cancer, colorectal cancer is the third most common cancer diagnosed in both men and women in the US. The estimated number of new colorectal cancer cases (data from 2015) is 132,700, and it is expected to cause about 49,000 deaths in 2015.

Exhibit 2. Colon Structure. Shown below are sections of the colon: the ascending colon, the transverse colon, the descending colon, and the sigmoid colon. Also shown are the small intestine, the cecum, and the rectum. The cecum, colon, rectum, and anal canal make up the large intestine. The cecum, ascending colon, and transverse colon makes up the upper, or proximal, colon; the descending colon and sigmoid colon make up the lower, or distal, colon.



Source: National Cancer Institute

Exhibit 3. Small polyps progress to cancer over a 10-year course of time. Most colorectal cancers begin as a polyp, a growth in the tissue that lines the inner surface of the colon or rectum and develops slowly over a period of 10-20 years. Polyps may be flat, or they may be raised. Raised polyps may grow on the inner surface of the colon or rectum like mushrooms without a stalk (sessile polyps), or they may grow like a mushroom with a stalk (pedunculated polyps). Polyps are common in people older than 50 years of age, and most are not cancers. However, a certain type of polyp, known as an adenoma, has a higher risk of becoming a cancer.



Source: Check-Cap

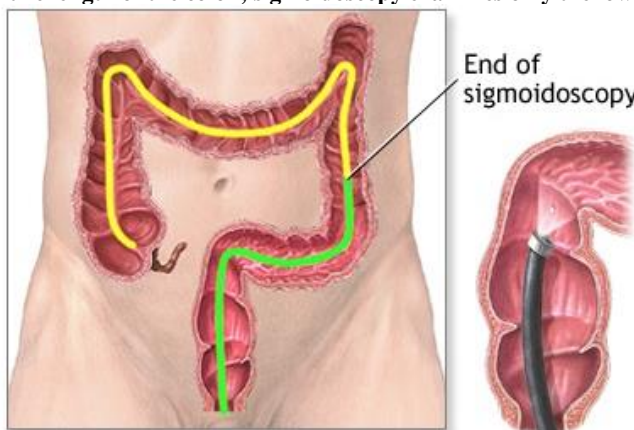
Competitive Landscape. Most polyps can be found and removed before they have the chance to turn into cancer. Screening can also result in finding colorectal cancer early, when it is highly curable. Currently, tests to detect colorectal cancer include stool test, colonoscopy, CT scan, and genetic testing, among others. The most common screening practice for colorectal cancer is colonoscopy.

Colonoscopy allows the observation of the entire length of the colon and rectum with a colonoscope, a thin, flexible, lighted tube with a small video camera on the end. It is inserted through the anus, and into the rectum and the colon with air pumping to expand the colon lining for a clearer visualization. The video camera on the end is connected to a display monitor so the doctor can see and closely examine the inside of the colon. Special instruments can be passed through the colonoscope to biopsy or remove any suspicious looking areas, such as polyps, if needed.

Before the colonoscopy, patients' colons and rectums must be empty and clean, so their inner linings can be seen clearly during the test. Patients are asked to limit or eliminate solid foods for a few days before the test. They may also be asked to drink 2-4 quarts of a salty liquid laxative the evening before and the morning of the procedure. Along with these dietary changes, patients may receive two enemas before the procedure, because the rectum and lower intestine must be empty so that the intestinal walls can be seen. In these cases, patients will need to try to hold the enema solution for at least five minutes before releasing it.

Sigmoidoscopy examines the rectum and sigmoid colon. Similar to the colonoscopy, sigmoidoscopy is a flexible lighted tube with a lens for viewing and a tool for removing tissue. This instrument is inserted through the anus into the rectum and sigmoid colon as air is pumped into the colon to expand it so the doctor can see the colon lining more clearly. During sigmoidoscopy, abnormal growths in the rectum and sigmoid colon can be removed for analysis (biopsied). The lower colon must be cleared of stool before sigmoidoscopy, but the preparation is less involved than that required for colonoscopy. People are usually not sedated for this test.

Exhibit 4. Colonoscopy examines the entire length of the colon; sigmoidoscopy examines only the lower third.



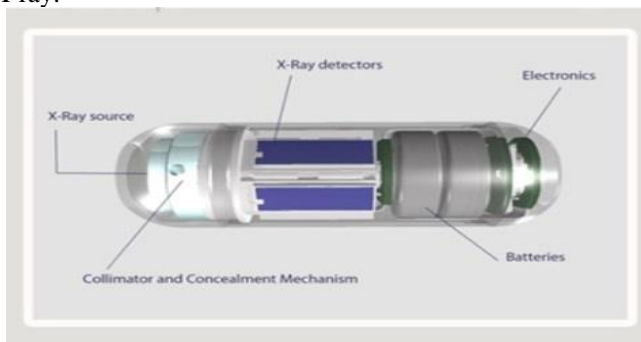
Source: *Animated Dissection of Anatomy for Medicine*

Fecal Occult Blood Tests (FOBT). Both polyps and colorectal cancers can bleed, and FOBT checks for tiny amounts of blood in feces (stool) that are not visible to the naked eye. (Blood in stool may also indicate the presence of conditions that are not cancer, such as hemorrhoids.) Currently, two types of FOBT are approved by the FDA to screen for colorectal cancer: guaiac FOBT (gFOBT) and the fecal immunochemical (or immunohistochemical) test (FIT, also known as iFOBT). With both types of FOBT, stool samples are collected by the patient using a kit, and the samples are returned to the doctor.

How Does the Imaging Capsule work? Check-Cap’s ingestible imaging capsule uses low-dose X-ray for CRC screening without compromising the high degree of specificity and sensitivity provided by traditional colonoscopy, while reducing the prep procedure, discomfort, and even the potential mortality rate associated with optical colonoscopy. The capsule is designed as non-invasive and prep-free device where the location of the device is always precisely known, as is the location of any captured images, such as a polyp, differentiating it from PillCam. It contains a device that transmits minimal radiation (a radiation exposure level equivalent to a regular chest X-ray) to inspect the colon content and reach the colon wall to detect any polyps. After the capsule is swallowed by the patient (the patient needs to drink an oral contrast solution to mix with colon contents before the test instead of a laxative preparation or change of diet), it will move passively through the gastrointestinal tract to produce 360-degree, angular scans of the lining of the colon. The polyps protruding inward into the colon can therefore be detected, and the capsule will then broadcast data to an external receiver. Check-Cap also has a supportive analysis system to receive the data transmitted from the colon to the proprietary software application, which can produce a two- and three-dimensional visualization of the colon.

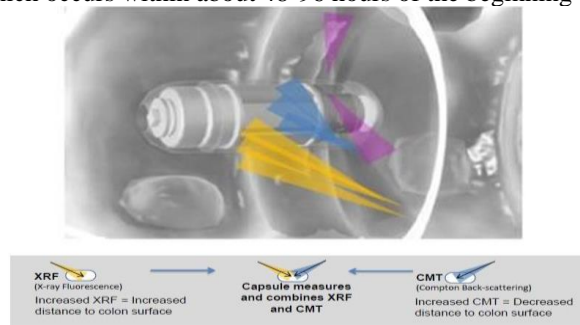
The imaging capsule is composed of: the X-ray source, including radioactive material sealed in a cylindrical housing; collimator, the radiation shield around the source, which absorbs most of the radiation (several radial holes enable the distribution of radiation in defined directions); X-ray sensor; activation circuit, which activates and/or deactivates the capsule; tilt sensor, which indicates capsule motion (3D acceleration); rotation motor, for rotating the collimator and X-ray source; batteries; data storage; and CPS coil, which transmits a continuous electromagnetic wave by an external localization system to track 3D position.

Exhibit 5. Check-Cap Imaging Capsule. The company’s patented technology uses reflected energy analysis to achieve an accurate diagnosis. The capsule measures X-ray fluorescence (XRF), which increases with distance to the colon surface, as well as Compton backscattering X-ray technology, which enables the capsule to “see-through” solid waste and capture a 360-degree, angular image of the colon surface. The technology uses motion and pressure detectors in order to provide the accurate location of any abnormal growth, only producing X-ray radiation while the capsule is moving. According to the company’s models, the entire process produces the amount of radiation equivalent to one chest X-ray.



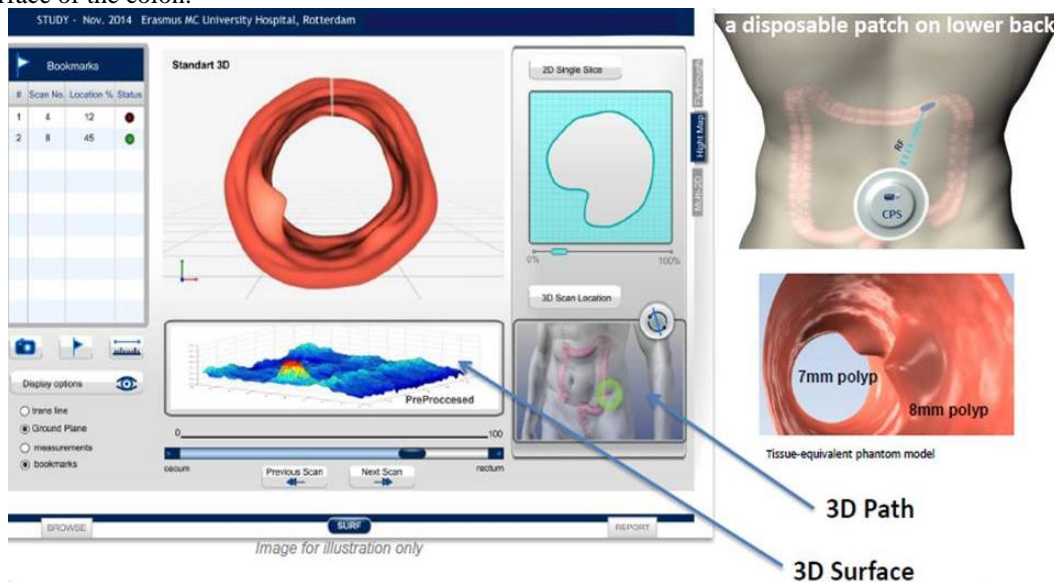
Source: Check-Cap

Exhibit 6. Proposed Mechanism of Action for the Ultra-Low-Dose X-Ray Imaging Capsule. The imaging capsule transmits information to a receiving device worn on the patient’s back called a capsule positioning system (CPS). The CPS is a small, disposable, and biocompatible sticker that is being designed to automatically track the imaging capsule’s positioning and orientation throughout the gastrointestinal tract transition, control the capsule scan mechanism through an embedded activation algorithm, capture imaging data from the capsule through radio frequency communication to a non-volatile memory device, and enable data retrieval through either wired or wireless communication to an external processor that stores the information for offline analysis. The receiver will also indicate when the capsule has been excreted, which occurs within about 48-96 hours of the beginning of the screening.



Source: Check-Cap

Exhibit 7. Data transmitted from the imaging capsule and reconstructed 3D image of the colon to indicate the size and location of the polyps identified. After the data have been collected from the receiver, a physician will then use the data viewer software application for analysis. Check-Cap’s proprietary software is designed to process the data, and produce a two- and three-dimensional visualization of the colon. It enables the physician to analyze the visualization and determine whether any anatomical anomalies are present on the surface of the colon.



Source: Check-Cap

Exhibit 8. Check-Cap’s imaging capsule detects polyps with no compromised sensitivity and specificity as compared to optical colonoscopy.



Source: Check-Cap

Modeling Assumptions:

1. Check-Cap's imaging capsule should begin to generate Europe 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 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 (50%) in our EU 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 9. 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 10. 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 EU 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 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.

Exhibit 11. FCFF 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 12. 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 13. 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

Income Statement

Check-Cap: Income Statement (\$000)													
: YE December 31	2018A	2019E	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	47,847	57,614	67,596	82,027	101,129	131,758	163,257
			0%	0%	0%	0%	25%	25%	25%	25%	25%	25%	25%
Research and Development	7,618	10,005	9,005	8,104	7,294	6,564	5,908	5,317	5,370	5,424	5,478	5,533	5,588
General and Administrative	3,445	3,567	3,995	4,594	5,054	5,306	5,572	5,850	6,201	6,573	6,968	7,386	7,829
Total expenses	11,063	13,572	13,000	12,698	12,347	11,871	59,327	68,782	79,167	94,025	113,575	144,676	176,674
Operating Income (Loss)	(11,063)	(13,572)	(13,000)	(11,367)	56,002	129,277	132,063	161,675	191,216	234,084	290,942	382,354	476,352
Finance income	473												
Finance expenses	-												
Total other income	473	-	-	-	-	-	-	-	-	-	-	-	-
Pretax Income	(10,590)	(13,572)	(13,000)	(11,367)	56,002	129,277	132,063	161,675	191,216	234,084	290,942	382,354	476,352
change in fair value of cash flow hedge	(13)												
Income Tax Benefit (Provision)	1	(8)	-	-	2,800	12,928	26,986	27,485	38,243	58,521	78,554	114,706	152,433
Tax Rate					5%	10%	15%	17%	20%	25%	27%	30%	32%
GAAP Net Income (loss)	(10,602)	(13,564)	(13,000)	(11,367)	53,202	116,349	105,076	134,190	152,973	175,563	212,388	267,648	323,920
GAAP-EPS	(2.61)	(1.68)	(0.71)	(0.49)	2.27	3.46	4.54	3.96	4.50	5.14	6.20	7.78	9.38
GAAP EPS (dil)	(2.61)	(1.68)	(0.38)	(0.28)	1.27	2.17	1.88	2.31	2.53	2.79	3.24	3.93	4.56
Wgtd Avg Shrs (Bas) - '000s	4,058	7,967	18,298	23,379	23,472	33,581	33,716	33,851	33,987	34,123	34,259	34,397	34,535
Wgtd Avg Shrs (Dil) - '000s	4,058	7,967	33,773	40,220	41,853	53,703	55,884	58,153	60,514	62,971	65,528	68,189	70,958

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 IP 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.

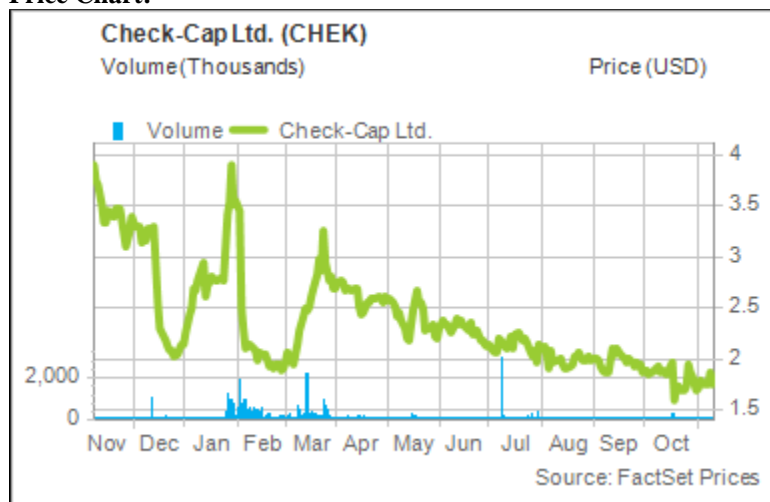
Companies mentioned in this report

General Electric (GE-Not Rated).

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

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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)	24	89%	2	8%
Market Perform (Neutral)	3	11%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	27	100%	2	7%

Accurate as of December 5, 2019

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