# INSTITUTIONAL RESEARCH



# **Medical Device**

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# Check-Cap (NASDAQ/CHEK)

BUY: Raises Capital Again & Again & Again

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May 11, 2020

Check-Cap announced a second and a third capital raise, selling initially 6.7M shares and equal number of warrants at \$0.60, then 7.5M shares & warrants, and over the weekend, 5M shares & warrants. The good news is the company now has cash, \$4M, \$4.5M and \$3M raised.

# **Investment Highlights**

Raise Capital as COVID Pushes Timelines. Check Cap ended the year with \$8M in cash and initiated a sequence of multiple raises as stated in the abstract above. The good news is the company should have enough capital to fund operations through the year. Our model has and continues to assume dilution and we recently lowered our price target to reflect this (4.21.20 from \$4.0 to \$2.0). In that same note we noted the likely impact of COVID as pushing timelines out, as such we understand the company's desire to raise capital.

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 Price Target						\$0.54 \$2.00
Estimates	F20	019A	F20	020E	F2	021E
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
	F20	019A	F2	020E	F2	021E
EPS (diluted)	\$	(1.73)	\$	(0.58)	\$	(0.17)
1Q March	\$	(0.44)	\$	(0.39)	\$	(0.04)
2Q June	\$	(0.41)	\$	(0.06)	\$	(0.04)
3Q September	\$	(0.42)	\$	(0.07)	\$	(0.05)
4Q December	\$	(0.46)	\$	(0.06)	\$	(0.05)
EBITDA/Share		(\$1.73)		(\$0.53)		(\$0.28)
EV/EBITDA (x)		0.0		0.0		0.0
Stock Data						
52-Week Range		\$0.44		-		\$2.80
Shares Outstanding (mil.	.)					25.2
Market Capitalization (m	il.)					\$14
Enterprise Value (mil.)						\$14
Debt to Capital						0%
Book Value/Share						\$0.53
Price/Book						2.3
Average Three Months T	radir	ng Volum	ne (	K)		72
Insider Ownership						2.6%
Institutional Ownership						1.4%
Short interest (mil.)						0.6%
Dividend / Yield				Ş	0.0	00/0.0%
Check-Cap Ltd. (CH	FK)					
Volume (Thousands)				Price	e(US	SD)



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 ≥40mm. Overall, the C-Scan System achieved a sensitivity of 66% in all patients (including patients with polyps <10mm), 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 110M (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 and April and May 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.

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#### **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
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%	1%	1%	1%	1%	1%
Sales (\$000)			\$ - 5		• - '	\$ -	\$ 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%
US Revenue (\$000)			\$ - 5	- :	-	\$ -	\$ 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%	2%	0%	0%	0%	0%	0%
Sales (\$000)	\$ -	\$ -	s - s	\$	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%
FILPovenue (\$000)	• -	٠ .	¢ _ ¢		700	\$ 41.010	\$ 84.245	\$ 112.491	\$ 133 320	\$ 152.154	\$ 171 245	\$ 100.506	\$ 210 200	\$ 230.087

Source: Dawson James

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17%

(539)

67

78,146

21,047

78,617

20%

(655)

69

91,871

91,285

18,912

195,333

142,593

141,699

17,371

27%

(967)

73

30%

193,853

192,752

18,176

(1,176)

75

32%

78

245,470

244,119

17,708

(1,429)

25%

(796)

71

111,117

110,392

17,593



**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 110M (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.

**Exhibit 3. FCFF Model** 

DCF Valuation Using FCF (mln):



EBIT		(13,836)	(13,453)	(12,316)	28,281	72,764	75,496	
Tax Rate		0%	0%	0%	5%	10%	15%	
EBIT(1-t)		(13,836)	(13,453)	(12,316)	26,867	65,487	64,172	
CapEx		(167)	(203)	(247)	(300)	(365)	(443)	
Depreciation		115	58	59	61	63	65	
Change in NWC								
FCF		(13,888)	(13,598)	(12,503)	26,628	65,186	63,794	
PV of FCF		(18,054)	(13,598)	(9,618)	15,756	29,670	22,336	
Discount Rate	30%							
Long Term Growth Rate	1%							
Terminal Cash Flow	850,206							
Terminal Value YE2025	61.672							

2030E

217.026

266

82.379

Source: Dawson James

NPV

NPV-Debt

NPV Per Share

Shares out (thousands)

**Exhibit 4. Discounted EPS Model** 

Current Year	2020
Year of EPS	2030
Earnings Multiple	10
Discount Factor	30%
Selected Year EPS	\$ 2.94
NPV	\$ 2

Source: Dawson James estimates

		Discount F	Rate and Earnir	ngs Multiple V 2030 E		s Constant	
	2.1	5%	10%	15%	20%	25%	30
Earnings Multiple	5	\$9.02	\$5.66	\$3.63	\$2.37	\$1.58 \$	1.0
	10	\$18.04	\$11.33	\$7.26	\$4.75	\$3.16 \$	2.13
	15	\$27.06	\$16.99	\$10.89	\$7.12	\$4.73 \$	3.20
	20	\$36.08	\$22.66	\$14.53	\$9.49	\$6.31 \$	4.20
	25	\$45.10	\$28.32	\$18.16	\$11.86	\$7.89 \$	5.33
	30	\$54.12	\$33.99	\$21.79	\$14.24	\$9.47 \$	6.39
	35	\$63.14	\$39.65	\$25.42	\$16.61	\$11.04 \$	7.40
	40	\$72.16	\$45.32	\$29.05	\$18.98	\$12.62 \$	8.53

Source: Dawson James

Exhibit 5. Sum of the Parts Model

Check-Cap	LT Gr	Discount Rate Yrs. to Mkt Peak		% Success	Peak Sales MM's	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

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## **Exhibit 6. Income Statement**

Eximple 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	-	<u> </u>	-			-	-	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
%CO	GS		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)		(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
operating moonre (2003)	(11,000)	(14,003)	(0,223)	(0,004)	(0,430)	(0,002)	(10,400)	(11,700)	33,021	120,521	101,742	101,000	150,510	200,110	250,001	302,007	470,023
Finance income	473	233															
Finance expenses	473	200															
Total other income	473	233				_	_	_	_								
Pretax Income	(10,590)		(2.220)	(2.004)	(2.400)		(13,453)		55.621	128.927	131,742	161.380	190.916	233,778	290.631	382.037	476.029
			(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)	1					-	.	. ,	,	, ,	,	, ,	,	,	,	
Income Tax Benefit (Provision)	1	(13)	-	-	-	-	-	-	2,781	12,893	26,938	27,435	38,183	58,445	78,470	114,611	152,329
TaxRate									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)	(0.39)	(0.11)	(0.13)	(0.10)	(0.72)	(0.28)	1.23	2.19	2.87	2.51	2.85	3.25	3.92	4.92	5.93
GAAP EPS (dil)	(2.61)	(1.73)	(0.39)	(0.06)	(0.07)	(0.06)	(0.58)	(0.17)	0.75	1.39	1.21	1.48	1.63	1.79	2.09	2.53	2.94
Wgtd Avg Shrs (Bas) - '000s	4,058	7,986	8,346	27,521	27,548	37,576	25,248	42,677	42,848	53,035	53,247	53,461	53,675	53,890	54,106	54,323	54,540
Wgtd Avg Shrs (Dil) - '000s	4,058	7,986	8,346	50,000	50,500	61,005	42,463	67,621	70,367	83,375	86,760	90,283	93,949	97,764	101,733	105,864	110,162
<u> </u>																	

Source: Dawson James

Check-Cap 5/11/2020



#### **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.

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#### 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

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The Firm does not make a market in the securities of the subject company(s). The Firm has NOT engaged in investment banking relationships with CHEK in the prior twelve months, as a manager or co-manager of a public offering and has NOT received compensation resulting from those relationships. The Firm may seek compensation for investment banking services in the future from the subject company(s). The Firm has NOT received any other compensation from the subject company(s) in the last 12 months for services unrelated to managing or co-managing of a public offering.

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Information about valuation methods and risks can be found in the "STOCK VALUATION" and "RISK ANALYSIS" sections of this report.

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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 Co	verage	Investment Banking			
Ratings Distribution	# 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%		

### **Analyst Certification:**

The analyst(s) whose name appears on this research report certifies that 1) all of the views expressed in this report accurately reflect his (their) personal views about any and all of the subject securities or issuers discussed; and 2) no part of the research analyst's compensation was, is, or will be directly or indirectly related to the specific recommendations or views expressed by the research analyst in this research report; and 3) all Dawson James employees, including the analyst(s) responsible for preparing this research report, may be eligible to receive non-product or service specific monetary bonus compensation that is based upon various factors, including total revenues of Dawson James and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.

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