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Can-Fite BioPharma Ltd. (NYSE/CANF)

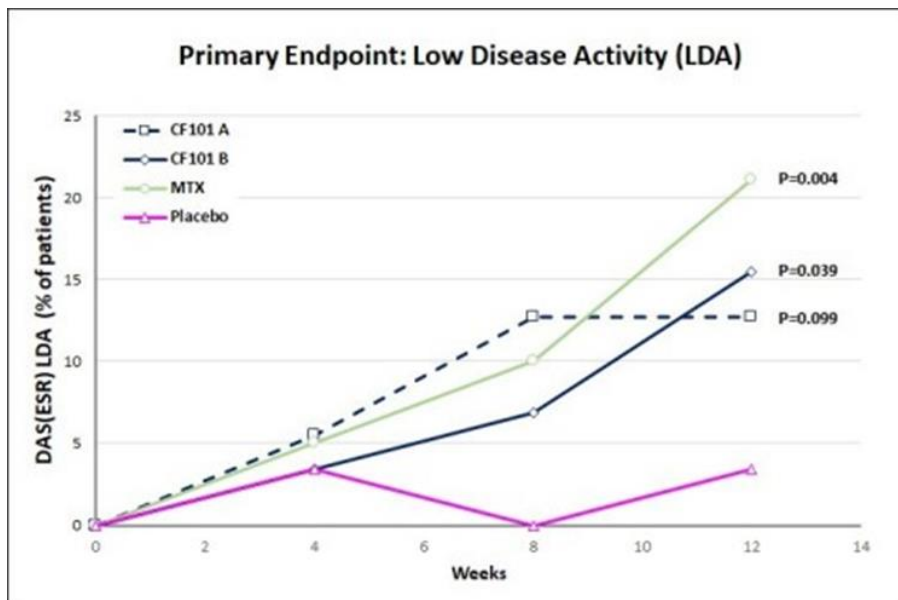
December 1, 2020
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BUY Rated - Reports Progress on all Fronts

Can-Fite announced 3Q20 results. The company spent just under \$2.5M and closed the period with \$10.2M. Management highlighted the status of the Comfort trial (Piclidenoson in Psoriasis) and regulatory approval (FDA) to evaluate Piclidenoson in COVID and a phase 2 data abstract at AASLD (NASH) for Namodenoson.

Investment Highlights

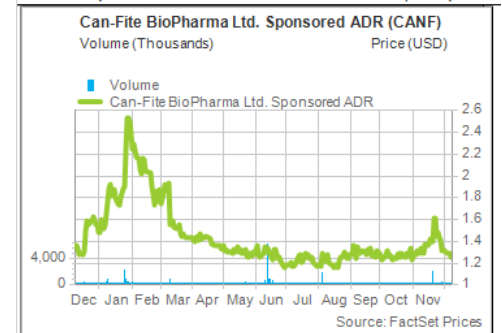
COMFORT Continues... An Independent Data Monitoring Committee recommended the Phase 3 psoriasis study continue. The IDMC also recommended that one of the dosing groups be dropped. The committee advised "no change" to the sample size, which we view as positive. Recall that the study is designed to evaluate the efficacy and safety of daily Piclidenoson, administered orally, compared to Apremilast (Otezla) and placebo in 407 patients with moderate-to-severe plaque psoriasis. The study is being conducted in five countries in Europe, Israel, and Canada. The primary endpoint is to be based on the percent of patients who achieve a PASI 75 score at week 16 vs. placebo. The secondary endpoints are to include non-inferiority vs. Otezla at week 32. Psoriasis alone is estimated to be a \$9B market.



Source: Can-Fite

Piclidenoson as a therapeutic in COVID. The trial is to assess efficacy through standard measures of clinical and respiratory status at Day 29, including the proportion of patients alive and free of respiratory failure, as well as the proportion discharged home without need for supplemental oxygen. Safety and pharmacokinetic data will also be captured.

Current Price	\$1.90		
Price Target	\$5.00		
Estimates	F2020E	F2021E	F2022E
Expenses (\$000s)	13,899	14,262	19,502
1Q March	4,474	3,280	4,485
2Q June	4,035	3,423	4,680
3Q September	2,690	3,708	5,070
4Q December	2,700	3,851	5,265
	F2020E	F2021E	F2022E
EPS (diluted)	(0.98)	(0.42)	(0.43)
1Q March	(0.47)	(0.13)	(0.10)
2Q June	(0.25)	(0.10)	(0.10)
3Q September	(0.15)	(0.11)	(0.11)
4Q December	(0.11)	(0.09)	(0.12)
EBITDA/Share	(\$0.15)	(\$0.16)	(\$1.08)
EV/EBITDA (x)	0.0	0.0	0.0
Stock Data			
52-Week Range	\$1.08	-	\$4.95
Shares Outstanding (mil.)	15.4		
Market Capitalization (mil.)	\$29.3		
Enterprise Value (mil.)	\$15.1		
Debt to Capital	0.0%		
Book Value/Share	\$4.52		
Price/Book	15.1		
Average Three Months Trading Volume (M)	0.4		
Insider Ownership	5.4%		
Institutional Ownership	8.0%		
Short interest (mil.)	2.2%		
Dividend / Yield	\$0.00/0.0%		


Please find Important Disclosures beginning on Page 5.

Data Presented at AASLD for Namodenoson:

- Anti-Inflammatory effect - a significant decrease in the liver enzymes ALT and AST and significant improvement in the positive cytokine adiponectin was recorded in the Namodenoson 25 mg treated group
- Reduced liver fat content - manifested by a significant reduction in % of liver fat volume assessed by MRI-PDFF and a decrease in the Controlled Attenuation Parameter (CAP - score ≥ 331) measured by FibroScan in the Namodenoson 25 mg group
- Decrease in FIB-4 and FAST - non-invasive tests showed anti-fibrosis effect in Namodenoson 25 mg group
- Decrease in body weight - a linear decrease in body weight was recorded in the 25 mg and 12.5 mg Namodenoson groups with a better effect in the higher dose
- Safety - Namodenoson continued to have a safe profile and was very well tolerated with no drug emergent severe adverse effects and no hepatotoxicity

Namodenoson in Liver Cancer – Pivotal is Next. The FDA has agreed with Can-Fite's proposed pivotal Phase 3 trial design. The study protocol and registration plan have also been submitted to the European Medicines Agency (EMA). Namodenoson is currently being used to treat liver cancer patients in a compassionate use program in Israel, which has enrolled seven patients. In addition, two patients who were enrolled in the Company's former Phase 2 study, who responded well to the drug, are continuing treatment. Those two advanced liver cancer patients have reached an overall survival of over 2.5 years while being treated with Namodenoson.

Valuation. We have removed Piclidenoson in RA but maintain it in Psoriasis, Namodenoson in HCC, and NAFLD. We apply a probability of success in these patient-based models. These metrics then flow into our valuation models. For Can-Fite, we apply a 30% discount rate, which is in addition to our therapeutic probability of success rate. We select 30% as the Company is not yet profitable, and most of the products are still dependent on the outcome of the clinical trial. Our valuation conclusion is an equally weighted average of our FCFF, EPS, and sum-of-the-parts analysis. We use a fully diluted end-year share count and assume multiple raises. The conclusion of this method is a \$5.00 price target.

Risks to our thesis include the following: (1) commercial; (2) regulatory; (3) clinical; (4) manufacturing; (5) financial; (6) liability; and (7) intellectual property.

Product Modeling Assumptions

1. We assume the program in RA does not continue but Psoriasis does to a second pivotal trial. If we assume a similar size, cost, and time for the studies, it suggests we could see U.S. top line data in a year from the current trial.
2. We assume Can-Fite may partner Piclidenoson (and Namodenoson). For the purpose of our model, we assume a sliding scale royalty at a base of 25% but rising to 30% based on sales levels. In accordance with this assumption, we only moderately increase G&A expenses as the Company is not likely to build a salesforce in this scenario.
3. We assume pricing of \$5,000 in the U.S. and \$3,000 in Europe with 2% year on year increases for Piclidenoson in Psoriasis, and the target population is assumed to be high A₃AR expressers.
4. A probability success factor of 50% to our models for Psoriasis.
5. We now assume Namodenoson is approved and launches (U.S. and Europe), for late-stage liver cancer in 2024.
6. We assume Namodenoson pricing of \$50,000 in the U.S. and \$35,000 in Europe with a 2% y/y increase.
7. A probability success factor of 50% is applied to our HCC model-based, which is based on Phase 2 data.
8. A probability success factor of 10% to our U.S. and EU models for NAFLD/NASH as the current Phase 2 study is exploratory, and the clinical development pathway for this indication is long and expensive and may require a partner to pay development costs. As such, we believe it's prudent to heavily discount the indication.
9. We do not include CF 602 for the ED indication in our model as the product is still in early stages of testing. We assume a partner is needed to move the project into the clinic.
10. We do not include any estimates for COVID.

Exhibit 1. U.S. Market Model for Psoriasis

Piclidenoson - CF101 (US)	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Psoriasis incidence	7,178,760	7,322,335	7,468,782	7,618,158	7,770,521	7,925,931	8,084,450	8,246,139	8,411,061	8,579,283	8,750,868	8,925,886	9,104,403
Increase in incidence	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Plaque psoriasis (80%)	5,743,008	5,857,868	5,975,026	6,094,526	6,216,417	6,340,745	6,467,560	6,596,911	6,728,849	6,863,426	7,000,695	7,140,709	7,283,523
Moderate to severe plaque psoriasis (17%)	976,311	995,838	1,015,754	1,036,069	1,056,791	1,077,927	1,099,485	1,121,475	1,143,904	1,166,782	1,190,118	1,213,920	1,238,199
Patients seeking treatment (84%)	820,102	836,504	853,234	870,298	887,704	905,458	923,568	942,039	960,880	980,007	999,699	1,019,693	1,040,087
Market Penetration						0.0%	3.0%	6.0%	7.0%	8.0%	9.0%	10.0%	11.0%
Patients receiving CF101						-	27,707	56,522	67,262	78,408	89,973	101,969	114,410
Annual cost of treatment						\$ 5,000	\$ 5,100	\$ 5,202	\$ 5,306	\$ 5,412	\$ 5,520	\$ 5,631	\$ 5,743
Increase in Price						2%	2%	2%	2%	2%	2%	2%	2%
Revenue ('000)						\$ -	\$ 141,306	\$ 294,029	\$ 356,893	\$ 424,356	\$ 496,687	\$ 574,170	\$ 657,103
Probability of Success						50%	50%	50%	50%	50%	50%	50%	50%
Total Revenue ('000)						\$ -	\$ 70,653	\$ 147,015	\$ 178,446	\$ 212,178	\$ 248,343	\$ 287,085	\$ 328,552

Source: Dawson James estimates, company reports

Exhibit 2. EU Market Model for Psoriasis

Piclidenoson - CF101 (EU)	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Psoriasis incidence	11,548,440	11,779,409	12,014,907	12,255,297	12,500,403	12,750,411	13,005,419	13,265,528	13,530,838	13,801,455	14,077,484	14,359,034	14,646,214
Increase in incidence	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Plaque psoriasis (80%)	9,238,752	9,423,527	9,611,998	9,804,238	10,000,322	10,200,329	10,404,335	10,612,422	10,824,670	11,041,164	11,261,987	11,487,227	11,716,971
Moderate to severe plaque psoriasis (17%)	1,570,588	1,602,000	1,634,040	1,666,720	1,700,055	1,734,056	1,768,737	1,804,112	1,840,194	1,876,998	1,914,538	1,952,829	1,991,885
Patients seeking treatment (84%)	1,319,294	1,345,680	1,372,593	1,400,045	1,428,046	1,456,607	1,485,739	1,515,454	1,545,763	1,576,678	1,608,212	1,640,376	1,673,184
Market Penetration						0.0%	2.0%	9.0%	10.0%	11.0%	12.0%	13.0%	14.0%
Patients receiving CF101						-	29,715	136,391	154,576	173,435	192,985	213,249	234,246
Price of treatment						\$ 3,000	\$ 3,060	\$ 3,121	\$ 3,184	\$ 3,247	\$ 3,312	\$ 3,378	\$ 3,446
Increase in Price						2%	2%	2%	2%	2%	2%	2%	2%
Revenue ('000)						\$ -	\$ 90,927	\$ 425,703	\$ 492,113	\$ 563,194	\$ 639,214	\$ 720,459	\$ 807,224
Probability of Success						50%	50%	50%	50%	50%	50%	50%	50%
Total Revenue ('000)						\$ -	\$ 45,464	\$ 212,852	\$ 246,056	\$ 281,597	\$ 319,607	\$ 360,229	\$ 403,612

Source: Dawson James estimates, company reports

Exhibit 3. Income Statement

Can-Fite Biopharma: Income Statement (\$000)																									
-YE December 31	2015A	2016A	2017A	2018A	2019A	1Q20A	2Q20A	3Q20a	4Q20E	2020E	2021E	1Q22E	2Q22E	3Q22E	4Q22E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	
Revenue:	165	170	847		2,032	198	204	211		613		-	-	-	-	-	-	134,394	163,128	193,963	227,024	262,440	300,347	340,889	
Picidenoson (CF-101), Rheumatoid Arthritis U.S.																									
Picidenoson (CF-101), Rheumatoid Arthritis EU																		280,207	583,056	667,272	757,342	853,600	956,399	1,066,112	
Picidenoson (CF-101), Psoriasis U.S.																		70,653	147,015	178,446	212,178	248,343	287,085	328,552	
Picidenoson (CF-101), Psoriasis EU																		45,464	212,852	246,056	281,597	319,607	360,229	403,612	
Namodenoson HCC U.S.																		7,940	41,304	51,567	62,592	74,424	87,110	100,899	
Namodenoson HCC EU																		11,095	57,716	72,057	87,463	103,996	121,722	140,711	
Namodenoson NASHNAFLD U.S.																		81,284	169,135	263,953	366,155	380,948	396,338	412,350	
Namodenoson NASHNAFLD EU																		-	67,654	140,775	219,693	304,758	317,071	329,880	
Total Product Sales	165	170	847		2,032	198	204	211		613		-	-	-	-	-	-	538,658	1,147,353	1,337,305	1,540,733	1,758,415	1,991,171	2,239,863	
Milestone From Gebro Holdings				3,820																					
Picidenoson (CF-101), Rheumatoid Arthritis U.S.																		33,599	48,938	58,189	68,107	78,732	90,104	102,267	
Royalty Rate from Global Partnership												25%	25%	25%	25%	#DIV/0!	#DIV/0!	25%	30%	30%	30%	30%	30%	30%	
Picidenoson (CF-101), Rheumatoid Arthritis EU																		70,052	174,917	200,182	227,202	256,080	286,920	319,834	
Royalty Rate from Global Partnership												25%	25%	25%	25%	#DIV/0!	#DIV/0!	25%	30%	30%	30%	30%	30%	30%	
Picidenoson (CF-101), Psoriasis U.S.																		17,663	36,754	44,612	53,044	62,086	71,771	82,138	
Royalty Rate from Global Partnership												25%	25%	25%	25%	#DIV/0!	#DIV/0!	39%	17%	18%	19%	19%	20%	20%	
Picidenoson (CF-101), Psoriasis EU																		17,663	36,754	44,612	53,044	62,086	71,771	82,138	
Royalty Rate from Global Partnership												25%	25%	25%	25%	#DIV/0!	#DIV/0!	39%	17%	18%	19%	19%	20%	20%	
Namodenoson HCC U.S.																		1,985	10,326	12,892	15,648	18,606	21,777	25,175	
Royalty Rate from Global Partnership												25%	25%	25%	25%	#DIV/0!	#DIV/0!	25%	25%	25%	25%	25%	25%	25%	
Namodenoson HCC EU																		2,774	14,429	18,014	23,615	28,079	32,865	37,992	
Royalty Rate from Global Partnership												25%	25%	25%	25%	#DIV/0!	#DIV/0!	25%	25%	25%	27%	27%	27%	27%	
Namodenoson NASHNAFLD U.S.																		20,321	42,284	65,988	93,223	96,989	100,908	104,984	
Royalty Rate from Global Partnership												25%	25%	25%	25%	#DIV/0!	#DIV/0!	25%	25%	25%	25%	25%	25%	25%	
Namodenoson NASHNAFLD EU																		-	16,914	35,194	54,923	76,190	79,268	82,470	
Royalty Rate from Global Partnership												25%	25%	25%	25%	#DIV/0!	#DIV/0!	25%	25%	25%	25%	25%	25%	25%	
Total royalties, collaborative revenue	-	-	-	4,452	2,032	198	204	211		613		-	-	-	-	-	-	164,057	381,315	479,682	588,808	678,848	755,384	836,997	
Total Revenue	-	170	847	4,452	2,032	198	204	211		613		-	-	-	-	-	-	164,057	381,315	479,682	588,808	678,848	755,384	836,997	
Expenses:																									
Partnership Costs including COGS																									
Research and Development	3,858	6,081	5,285	6,075	10,976	3,771	3,283	2,001	2,000	11,055	11,276	2,645	2,760	2,990	3,105	11,502	11,732	11,966	12,206	12,450	12,699	12,953	13,212	13,476	
General and Administrative	2,725	2,726	2,956	3,159	3,059	703	752	689	700	2,844	2,986	1,840	1,920	2,080	2,160	8,000	12,000	12,600	13,230	13,892	14,586	15,315	16,081	16,885	
Total Expenses	6,583	8,807	8,241	9,234	14,035	4,474	4,035	2,690	2,700	13,899	14,262	4,485	4,680	5,070	5,265	19,502	23,732	24,566	24,636	24,940	25,249	25,568	25,887	26,206	
Operating Income (Loss)	(6,418)	(8,637)	(7,394)	(5,414)	(12,003)	(4,276)	(3,831)	(2,479)	(2,700)	(13,286)	(14,262)	(4,485)	(4,680)	(5,070)	(5,265)	(19,502)	(23,732)	(11,509)	(11,321)	(11,142)	(10,961)	(10,785)	(10,613)	(10,440)	
Finance expenses	564	178	1,102	1,204	693																				
Finance income	(1,920)	(1,820)	(2,999)	(51)	3,109	(66)	(62)	(96)																	
Total Other Income	(1,356)	(1,642)	(1,897)	1,153	2,416	(66)	(62)	(96)																	
Pre-tax Income	5,066	(6,957)	(4,993)	(6,571)	(9,587)	(4,342)	(3,769)	(2,383)	(2,700)	(13,194)	(14,262)	(4,485)	(4,680)	(5,070)	(5,265)	(19,502)	(23,732)	112,557	298,511	386,475	484,487	562,659	626,533	694,643	
Taxes on income	4	29		4																					
Adjustments arising from translating financial statements of foreign operations		9	30			(715)			715																
Remeasurement loss from defined benefit plans	99																								
Tax Rate																									
GAAP Net Income (Loss)	5,066	(6,966)	(4,993)	(6,571)	(9,587)	(4,342)	(3,769)	(2,383)	(2,700)	(13,194)	(14,262)	(4,485)	(4,680)	(5,070)	(5,265)	(19,502)	(23,732)	112,557	298,511	386,475	484,487	562,659	626,533	694,643	
Total comprehensive loss	5,066	(6,957)	(4,993)	(6,571)	(9,587)	(4,342)	(3,769)	(2,383)	(2,700)	(13,194)	(14,262)	(4,485)	(4,680)	(5,070)	(5,265)	(19,502)	(23,732)	118,185	274,631	340,098	363,365	393,861	426,042	458,464	
GAAP-EPS	#DIV/0!	(0.25)	(0.14)	(0.17)	(1.77)	(0.47)	(0.25)	(0.15)	(0.11)	(0.98)	(0.42)	(0.10)	(0.10)	(0.11)	(0.12)	(0.43)	(0.52)	2.47	6.53	8.42	10.51	12.16	13.48	14.89	
GAAP-EPS (Dil)																									
Wght Avg ADR Shrs (Bas) - '000s	-	28,096	32,994	38,793	5,833	9,222	15,000	15,414	25,429	16,266	35,140	45,115	45,160	45,205	45,251	45,183	45,364	45,546	45,728	45,911	46,095	46,280	46,465	46,651	
Wght Avg ADR Shrs (Dil) - '000s	-	28,096	32,994	41,953	8,910	13,833	15,000	15,414	30,429	18,669	58,914	75,205	75,280	75,356	75,431	75,318	75,620	75,923	76,227	76,532	76,839	77,147	77,456	77,766	

Source: Dawson James Securities, company reports

Risk Analysis

In addition to the typical risks associated with development stage specialty pharmaceutical companies, potential risks specific to Can-Fite are as follows:

Financial risk. The Company may need to raise capital in the marketplace, and there can be no assurances that the Company will be able to successfully raise capital and/or do so on favorable terms.

Clinical and regulatory risk. Lead products must start and complete clinical trials. Trials may not produce results sufficient for regulatory approval.

Partnership risk. Can-Fite may seek partnerships for clinical development support and commercialization. We have no specific knowledge of any discussions with possible partners today, and there can be no assurances that the Company will be able to secure a favorable partnership.

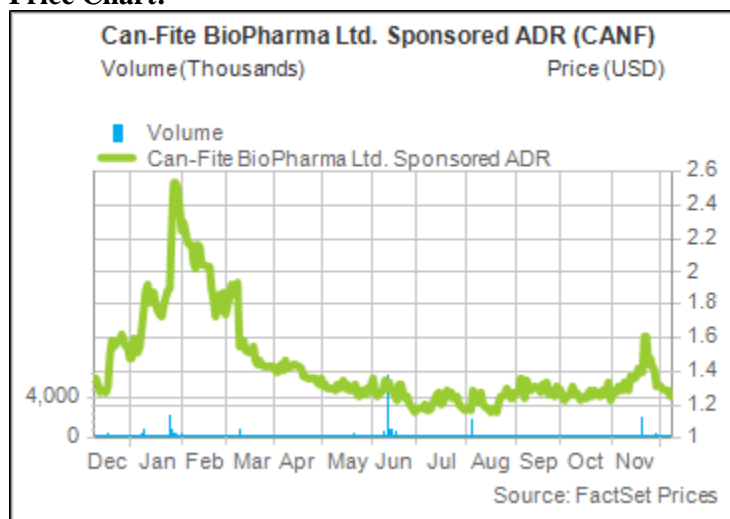
Commercial risk. There are no assurances that the Company will be able to secure favorable pricing, commercially launch products, and achieve significant market share to become profitable.

Legal and intellectual property risk. The Company may have to defend its patents and technical know-how, and there can be no assurances that the patents will not be infringed or will be held as valid if challenged, and or that the Company may infringe on third parties' patents.

Companies mentioned in this report:

Important Disclosures:

Price Chart:



Price target and rating changes over the past three years:

- Initiated – Buy – December 13, 2018 – Price Target \$7
- Update – Buy – March 26, 2019 – Price Target \$6
- Update – Buy – May 21, 2019 – Price Target \$9 (adjusted down after reverse stock split).
- Update – Buy – August 7, 2019 – Price Target \$9
- Update – Buy – September 11, 2019 – Price Target \$9
- Update – Buy – September 18, 2019 – Price Target \$9
- Update – Buy – September 23, 2019 – Price Target \$9
- Update – Buy – October 15, 2019 – Price Target \$9
- Update – Buy – October 31, 2019 – Price Target \$9
- Update – Buy – November 4, 2019 – Price Target \$9
- Update – Buy – December 2, 2019 – Price Target \$9
- Update – Buy – December 11, 2019 – Price Target \$9
- Update – Buy – February 3, 2020 – Price Target \$9

Update – Buy – February 19, 2020 – Price Target \$9
Update – Buy – March 5, 2020 – Price Target \$9
Update – Buy – April 13, 2020 – Price Target \$9
Update – Buy – April 20, 2020 – Price Target \$9
Update – Buy – May 19, 2020 – Price Target \$9
Update – Buy – June 1, 2020 – Price Target \$9
Update – Buy – June 9, 2020 – Price Target \$9
PT Change – Buy – June 10, 2020 – Price Target lowered from \$9 to \$7.0
Update – Buy – June 30, 2020 – Price Target \$7
Update – Buy – July 30, 2020 – Price Target \$7
Update – Buy – August 31, 2020 – Price Target \$7
PT Change – Buy – October 6, 2020 – Price Target \$5
Update – Buy – November 16, 2020 – Price Target \$5
Update – Buy – December 1, 2020 – Price Target \$5

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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 CANF 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 received 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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Although the statements in this report have been obtained from and are based upon recognized statistical services, issuer reports or communications, or other sources that the Firm believes to be reliable, we cannot guarantee their accuracy. All opinions and estimates included in this report constitute the analyst's judgment as of the date of this report and are subject to change without notice.

Information about valuation methods and risks can be found in the "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.

Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	21	78%	4	19%
Market Perform (Neutral)	6	22%	1	17%
Market Underperform (Sell)	0	0%	0	0%
Total	27	100%	5	19%

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.