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## Can-Fite BioPharma Ltd. (NYSE/CANF)

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### BUY Rated – NASH 2b is to be.

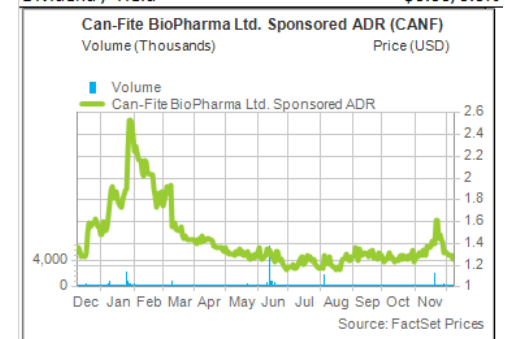
Can-Fite announced that the NASH program is alive and well and will advance to a Phase 2b study. The protocol is being developed in conjunction with leading Key Opinion Leaders (KOLs) in NASH and liver diseases including Dr. Scott Friedman, Chief of the Division of Liver Diseases at the Icahn School of Medicine at Mount Sinai in New York (whom we met last year) and Dr. Stephen A. Harrison, Medical Director of Pinnacle Clinical Research. The Phase IIb NASH protocol intends to dose patients with 25 mg Namodenoson and measure safety and efficacy endpoints including liver biopsy.

### Investment Highlights

**Earlier this year, CanFite Announced Phase 2 Data:** An in-depth review of the Phase 2 data revealed 25 mg of Namodenoson was found to resolve significantly all cases of NASH, representing 25% of the 25 mg treated group, as compared to an increase in new NASH cases in the placebo group from a baseline of 0 to 5.9%.

- Additional findings from the Phase 2 study of Namodenoson in the treatment of NASH. The company reported topline results from the Phase 2 study indicating Namodenoson had achieved its efficacy endpoints in a dose dependent and statistically significant manner, while continuing to demonstrate a good safety profile.
- In the Phase 2 study, 25 mg of Namodenoson was shown to reduce hepatic fibrosis (scar tissue in the liver resulting from the liver trying to repair itself), reduce steatosis (fat buildup in the liver), and improve the FAST score, a measure for NASH (liver stiffness and an enzymatic biomarker of liver damage).
- Patients treated with 25 mg of Namodenoson had a statistically significant reduction in hepatic fibrosis as measured by the Fibrosis-4 (FIB-4) score, as compared to placebo. FIB-4 change from baseline improved by -0.089 in patients dosed with 25 mg of Namodenoson, as compared to the placebo group which deteriorated from baseline by 0.042 points, with  $p=0.026$ . FIB-4 is a non-invasive marker of hepatic fibrosis consisting of four parameters including age, platelet counts, and two liver enzymes, aspartate aminotransferase (AST) and alanine aminotransferase (ALT), which are elevated in a damaged liver.
- In the Namodenoson 25 mg treated group, the proportion of patients with high steatosis scores declined from 37.5% to 13.3% of the population, as compared to the placebo treated group in which the proportion of patients with high steatosis scores decreased from 37.5% to 35.3% of the population, with  $p=0.08$ . Steatosis was assessed by Controlled Attenuation Parameter (CAP) measurement of the FibroScan, a non-invasive marker of hepatic steatosis.
- 25% of patients randomized into the Namodenoson 25 mg dosed group had NASH at baseline, as compared to none in the placebo group, which comprised patients who had NAFLD without NASH at baseline. Following 12 weeks of treatment, all NASH cases were resolved in patients treated with 25 mg of Namodenoson, as compared to new NASH that developed in the placebo group representing 5% of that population, with  $p<0.009$ . NASH was evaluated by FibroScan-AST (FAST) score, a noninvasive marker of NASH, the severe form of NAFLD (equivalent to biopsy findings of  $NAS\geq 4$ ,  $F\geq 2$ ), measured by FibroScan elastography, CAP and serum AST.

Current Price	\$1.83		
Price Target	\$5.00		
<b>Estimates</b>	<b>F2020A</b>	<b>F2021E</b>	<b>F2022E</b>
Expenses (\$000s)	17,093	16,669	19,648
1Q March	4,474	3,834	4,519
2Q June	4,035	4,001	4,715
3Q September	4,211	4,334	5,108
4Q December	4,373	4,501	5,305
	<b>F2019A</b>	<b>F2021E</b>	<b>F2022E</b>
EPS (diluted)	(1.17)	(0.49)	(0.39)
1Q March	(0.47)	(0.15)	(0.09)
2Q June	(0.25)	(0.11)	(0.09)
3Q September	(0.28)	(0.12)	(0.10)
4Q December	(0.17)	(0.10)	(0.11)
EBITDA/Share	(\$0.15)	(\$0.16)	(\$1.08)
EV/EBITDA (x)	0.0	0.0	0.0
<b>Stock Data</b>			
52-Week Range	\$1.08	-	\$4.95
Shares Outstanding (mil.)	15.4		
Market Capitalization (mil.)	\$28.2		
Enterprise Value (mil.)	\$10.3		
Debt to Capital	0.0%		
Book Value/Share	\$4.52		
Price/Book	15.1		
Average Three Months Trading Volume (M)	0.3		
Insider Ownership	5.4%		
Institutional Ownership	8.9%		
Short interest (mil.)	2.8%		
Dividend / Yield	\$0.00/0.0%		



**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  $\geq 331$ ) 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 A<sub>3</sub>AR 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%
<b>Total Revenue ('000)</b>						\$ -	\$ 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	12,014,997	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%
<b>Total Revenue ('000)</b>						\$ -	\$ 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)	2015A	2016A	2017A	2018A	2019A	1Q20A	2Q20E	3Q20E	4Q20E	2020E	1Q21E	2Q21E	3Q21E	4Q21E	2021E	1Q22E	2Q22E	3Q22E	4Q22E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E			
<b>Revenue:</b>	165	170	847		2,032	198	204			402																					
Picidenoson (CF-101), Rheumatoid Arthritis U.S.																						134,394	163,138	193,963	227,034	262,440	300,347	340,889			
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	100,699			
Namodenoson HCC EU																						11,095	57,716	72,057	87,463	103,996	121,722	140,711			
Namodenoson NASH/NAFLD U.S.																						81,284	169,135	263,953	366,155	380,948	396,338	412,350			
Namodenoson NASH/NAFLD EU																						67,654	140,775	219,693	304,758	317,071	329,880				
<b>Total Product Sales</b>	165	170	847	3,820	2,032	198	204			402											538,658	1,147,533	1,237,365	1,540,733	1,753,416	1,931,171	2,239,863				
Missionone From Gebro Holdings																															
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%	30%	30%	30%	30%	30%	30%	30%		
Picidenoson (CF-101), Rheumatoid Arthritis EU																						70,052	174,917	200,182	227,202	256,080	286,930	319,834			
Royalty Rate from Global Partnership																						25%	30%	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%	25%	25%	25%	25%		
Picidenoson (CF-101), Psoriasis EU																						17,663	36,754	44,612	53,044	62,086	71,771	82,138			
Royalty Rate from Global Partnership																						39%	17%	18%	19%	19%	20%	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%	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%	25%	25%	25%	25%		
Namodenoson NASH/NAFLD 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%	25%	25%	25%	25%		
Namodenoson NASH/NAFLD EU																						16,914	35,194	54,923	76,190	79,268	82,470				
Royalty Rate from Global Partnership																						25%	25%	25%	25%	25%	25%	25%	25%		
<b>Total royalties, collaborative revenue</b>				4,452	2,032	198	204			402												164,057	381,315	479,682	568,808	678,848	755,384	836,997			
<b>Total Revenue</b>		170	847	4,452	2,032	198	204			402												164,057	381,315	479,682	568,808	678,848	755,384	836,997			
<b>Expenses:</b>																															
Partnership Costs including COGS																							26,833	57,368	66,855	77,037	87,921	99,559	111,993		
Research and Development	%COGS	3,858	6,081	5,285	6,075	10,976	3,771	3,283	2,911	3,023	11,196	2,626	2,741	2,969	3,083	11,419	2,679	2,795	3,028	3,145	11,648	11,881	12,118	12,361	12,608	13,117	13,380	13,647			
General and Administrative	%SG&A	2,725	2,726	2,956	3,159	3,059	703	752	1,300	1,350	5,000	1,208	1,260	1,365	1,418	5,250	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		
<b>Total Expenses</b>		6,583	8,807	8,241	9,234	14,035	4,474	4,035	4,211	4,373	17,093	3,834	4,001	4,334	4,501	16,669	4,519	4,715	5,108	5,305	19,648	23,881	21,651	22,958	23,936	24,463	25,019	25,526	26,042		
Operating Income (Loss)		(6,418)	(8,637)	(7,394)	(5,414)	(12,003)	(4,276)	(3,831)	(4,211)	(4,373)	(16,691)	(3,834)	(4,001)	(4,334)	(4,501)	(16,669)	(4,519)	(4,715)	(5,108)	(5,305)	(19,648)	(23,881)	112,405	298,356	386,317	484,325	562,494	626,365	694,472		
Finance expenses		564	178	1,102	1,204	893																									
Finance income		(1,920)	(1,820)	(2,999)	(51)	3,108	(66)	(62)																							
<b>Total Other Income</b>		(1,356)	(1,642)	(1,897)	1,153	2,416	(66)	(62)																							
<b>Pretax Income</b>		5,062	(6,955)	(4,963)	(6,567)	(9,587)	(4,342)	(3,769)	(4,211)	(4,373)	(16,691)	(3,834)	(4,001)	(4,334)	(4,501)	(16,669)	(4,519)	(4,715)	(5,108)	(5,305)	(19,648)	(23,881)	112,405	298,356	386,317	484,325	562,494	626,365	694,472		
Taxes on income		4	29		4																										
Adjustments arising from translating financial statements of foreign operations			9	30			(715)																5,620	23,869	46,358	121,081	168,748	200,437	236,120		
Remeasurement loss from defined benefit plans		99																													
<b>Tax Rate</b>																							5%	8%	12%	25%	30%	32%	34%		
<b>GAAP Net Income (Loss)</b>		5,066	(6,966)	(4,993)	(6,571)	(9,587)	(4,342)	(3,769)	(4,211)	(4,373)	(16,691)	(3,834)	(4,001)	(4,334)	(4,501)	(16,669)	(4,519)	(4,715)	(5,108)	(5,305)	(19,648)	(23,881)	112,405	298,356	386,317	484,325	562,494	626,365	694,472		
<b>Total comprehensive loss</b>		5,066	(6,957)	(4,993)	(6,571)	(9,587)	(4,342)	(3,769)	(4,211)	(4,373)	(16,691)	(3,834)	(4,001)	(4,334)	(4,501)	(16,669)	(4,519)	(4,715)	(5,108)	(5,305)	(19,648)	(23,881)	118,026	274,488	339,959	363,244	393,746	425,028	458,351		
<b>GAAP-EPS</b>	#DNV0!		(0.25)	(0.14)	(0.17)	(1.77)	(0.47)	(0.25)	(0.28)	(0.17)	(1.03)	(0.15)	(0.11)	(0.12)	(0.10)	(0.48)	(0.09)	(0.09)	(0.10)	(0.11)	(0.39)	(0.47)	2.23	5.89	7.59	9.48	10.97	12.16	13.43		
GAAP-EPS (Dil)			(0.14)	(0.16)	(1.35)	(0.31)	(0.13)	(0.14)	(0.10)	(0.56)	(0.08)	(0.07)	(0.07)	(0.06)	(0.28)	(0.06)	(0.06)	(0.06)	(0.07)	(0.25)	(0.30)	1.39	3.68	4.75	5.93	6.85	7.60	8.40			
Wght Avg ADR Shrs (Bas) - '000s		28,096	32,994	38,793	5,833	9,222	15,000	15,150	25,165	16,134	25,190	35,000	35,035	45,070	35,074	50,000	50,050	50,100	50,150	50,075	50,276	50,477	50,679	50,882	51,086	51,291	51,496	51,703			
Wght Avg ADR Shrs (Dil) - '000s		28,096	32,994	41,953	8,910	13,833	30,000	30,300	45,330	29,896	45,376	60,000	60,060	70,120	58,889	80,000	80,060	80,160	80,240	80,120	80,441	80,763	81,087	81,412	81,738	82,065	82,394	82,724			

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.

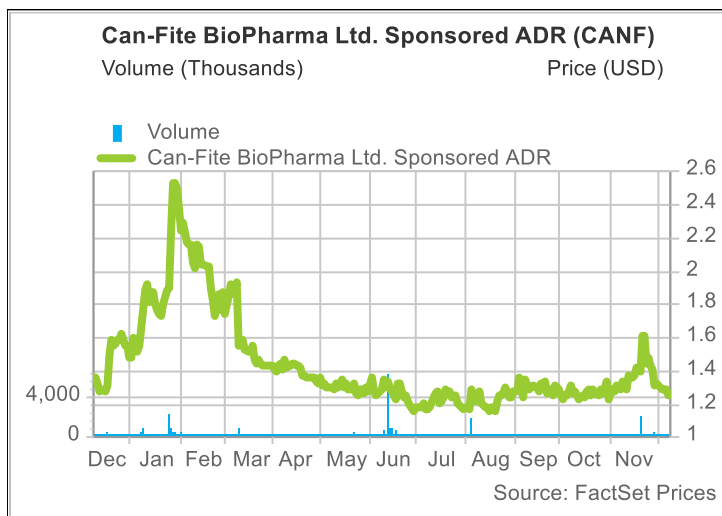
**Commercial risk.** There are no assurances that the Company will be able to secure favorable pricing, commercially launch products, and achieve significant market share to become profitable.

**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  
Update – Buy – December 17, 2020 – Price Target \$5

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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%	5	24%
Market Perform (Neutral)	6	22%	1	17%
Market Underperform (Sell)	0	0%	0	0%
Total	27	100%	6	22%

**Analyst Certification:**

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