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Can-Fite BioPharma Ltd. (NYSE/CANF)

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BUY-Rated – Piclidenoson Trial Hits the ¾ Mark

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Can-Fite announced that 75% of patients have been enrolled in its P3 Comfort™ study designed to establish Piclidenoson's superiority compared to placebo and non-inferiority compared to Apremilast (Otezla®) in patients with moderate to severe plaque psoriasis. The Company expects to complete enrollment in Q3 2021 and report topline results in Q4 2021.

Investment Highlights

COMFORT Continues... Now at 75% Enrolled. An Independent Data Monitoring Committee (late last year) recommended the Piclidenoson 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. The Psoriasis market is worth \$9B.

What is Piclidenoson (CF101)? It is an oral A₃AR Agonist being developed as a treatment for rheumatoid arthritis and psoriasis. Piclidenoson has also shown potential for other inflammatory diseases such as Crohn's disease. The orally bioavailable A₃AR agonist has a half-life of approximately eight to nine hours in circulation. Piclidenoson is a highly selective A₃AR agonist and is a nucleoside derivative with a molecular weight of 510.29 daltons. Piclidenoson is not metabolized in the body and is secreted unchanged. Binding of Piclidenoson to A₃AR inhibits the production of inflammatory cytokines including Tumor Necrosis Factor Alpha (TNF-α), Interleukin (IL) -6, IL-1, and chemokines, or small cytokines, such as MMP, by signaling through the NF-κB pathway and the PKB/AKT pathway. The net result is believed to be deregulation of the Wnt and the NF-κB pathways. NF-κB is a transcription factor responsible for the expression of pro-inflammatory cytokines, and it is activated by intra and extra cellular stimuli such as TNF-α and IL-1 (and other cytokines and chemokines). Dysregulation of Wnt and NF-κB signaling induces inflammatory conditions/diseases.

Valuation. We evaluate Piclidenoson in Psoriasis but do not include COVID, 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 projected 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.

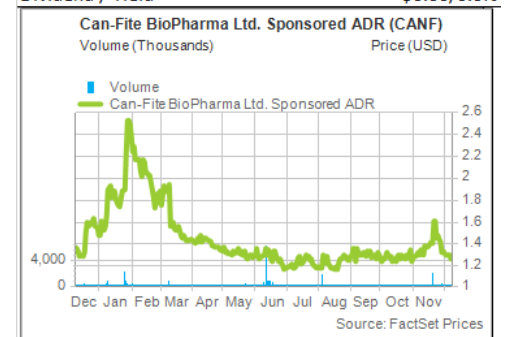
Current Price	\$2.34
Price Target	\$5.00

Estimates	F2020A	F2021E	F2022E
Expenses (\$000s)	14,902	15,289	20,434
1Q March	4,474	3,516	4,700
2Q June	4,035	3,669	4,904
3Q September	2,690	3,975	5,313
4Q December	3,703	4,128	5,517

	F2020A	F2021E	F2022E
EPS (diluted)	(1.02)	(0.45)	(0.41)
1Q March	(0.47)	(0.14)	(0.09)
2Q June	(0.25)	(0.10)	(0.10)
3Q September	(0.16)	(0.11)	(0.11)
4Q December	(0.14)	(0.09)	(0.11)

EBITDA/Share	(\$0.15)	(\$0.16)	(\$1.08)
EV/EBITDA (x)	0.0	0.0	0.0

Stock Data			
52-Week Range	\$1.51	-	\$4.39
Shares Outstanding (mil.)	17.2		
Market Capitalization (mil.)	\$40.2		
Enterprise Value (mil.)	\$18.7		
Debt to Capital	0.0%		
Book Value/Share	\$4.52		
Price/Book	4.5		
Average Three Months Trading Volume (M)	0.3		
Insider Ownership	1.2%		
Institutional Ownership	12.3%		
Short interest (mil.)	4.1%		
Dividend / Yield	\$0.00/0.0%		



Please find Important Disclosures beginning on Page 4.

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 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 HCC and NASH & NAFLD

	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Namodenoson - CF102 (US)													
Hepatocellular Carcinoma incidence	42,355	43,202	44,066	44,947	45,846	46,763	47,696	48,652	49,625	50,618	51,630	52,663	53,716
Increase in incidence	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
% of deaths due to Sorafenib in patients with Barcelona Clinic Liver Cancer stage CHCC (84%)	27,107	27,849	28,202	28,768	29,341	29,928	30,527	31,137	31,760	32,395	33,043	33,704	34,378
Market Penetration					0.0%	0.0%	1.0%	5.0%	8.0%	7.0%	8.0%	9.0%	10.0%
Patients receiving CF101					-	-	305	1,557	1,906	2,268	2,643	3,033	3,438
Price of treatment					\$ 50,000	\$ 51,000	\$ 52,020	\$ 53,060	\$ 54,122	\$ 55,204	\$ 56,308	\$ 57,434	\$ 58,583
Increase in Price					2%	2%	2%	2%	2%	2%	2%	2%	2%
Revenue ('000)					\$ -	\$ -	\$ 15,880	\$ 82,808	\$ 103,135	\$ 125,185	\$ 148,848	\$ 174,220	\$ 201,398
Probability of Success					50%	50%	50%	50%	50%	50%	50%	50%	50%
Total Revenue ('000)					\$ -	\$ -	\$ 7,940	\$ 41,304	\$ 51,567	\$ 62,592	\$ 74,424	\$ 87,110	\$ 100,658
Namodenoson - CF102 (EU)													
Hepatocellular Carcinoma incidence	54,111	55,193	56,297	57,423	58,572	59,743	60,938	62,157	63,400	64,668	65,961	67,280	68,626
Increase in incidence	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
% of death occurrence due to Sorafenib in patients with Barcelona Clinic Liver Cancer stage C HCC (64%)	34,631	35,324	36,030	36,751	37,486	38,236	39,000	39,780	40,576	41,387	42,215	43,060	43,921
Market Penetration					0.0%	0.0%	1.0%	5.0%	6.0%	7.0%	8.0%	9.0%	10.0%
Patients receiving CF101					-	-	609	3,108	3,804	4,527	5,277	6,055	6,863
Price of treatment					\$ 35,000	\$ 35,700	\$ 36,414	\$ 37,142	\$ 37,885	\$ 38,643	\$ 39,416	\$ 40,204	\$ 41,008
Increase in Price					2%	2%	2%	2%	2%	2%	2%	2%	2%
Revenue ('000)					\$ -	\$ -	\$ 22,190	\$ 115,432	\$ 144,115	\$ 174,927	\$ 207,993	\$ 243,445	\$ 281,422
Probability of Success					50%	50%	50%	50%	50%	50%	50%	50%	50%
Total Revenue ('000)					\$ -	\$ -	\$ 11,095	\$ 57,716	\$ 72,057	\$ 87,463	\$ 103,996	\$ 121,722	\$ 140,711
Namodenoson - CF102 (US)													
NAFLD/NASH	11,648,440	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%
Market Penetration					0.25%	0.50%	0.75%	1.00%	1.00%	1.00%	1.00%	1.00%	1.00%
Patients receiving CF101					-	-	32,514	66,328	101,481	138,015	140,775	143,590	146,462
Price of treatment					\$ 25,000	\$ 25,500	\$ 26,010	\$ 26,530	\$ 27,061	\$ 27,601	\$ 28,154	\$ 28,719	\$ 29,296
Increase in Price					2%	2%	2%	2%	2%	2%	2%	2%	2%
Revenue ('000)					\$ -	\$ -	\$ 812,839	\$ 1,691,355	\$ 2,639,528	\$ 3,661,554	\$ 3,809,480	\$ 3,963,383	\$ 4,123,504
Probability of Success					10%	10%	10%	10%	10%	10%	10%	10%	10%
Total Revenue ('000)					\$ -	\$ -	\$ 81,284	\$ 169,135	\$ 263,953	\$ 366,155	\$ 380,948	\$ 396,338	\$ 412,350
Namodenoson - CF102 (EU-5)													
NAFLD/NASH	11,648,440	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%
Market Penetration					0.00%	0.25%	0.50%	0.75%	1.00%	1.00%	1.00%	1.00%	1.00%
Patients receiving CF101					-	-	33,164	67,654	103,511	140,775	143,590	146,462	149,393
Price of treatment					\$ 20,000	\$ 20,400	\$ 20,800	\$ 21,224	\$ 21,649	\$ 22,082	\$ 22,523	\$ 22,970	\$ 23,424
Increase in Price					2%	2%	2%	2%	2%	2%	2%	2%	2%
Revenue ('000)					\$ -	\$ -	\$ 676,542	\$ 1,407,748	\$ 2,196,932	\$ 3,047,584	\$ 3,170,707	\$ 3,298,803	\$ 3,431,927
Probability of Success					10%	10%	10%	10%	10%	10%	10%	10%	10%
Total Revenue ('000)					\$ -	\$ -	\$ 67,654	\$ 140,775	\$ 219,693	\$ 304,758	\$ 317,071	\$ 329,880	\$ 343,203

Source: Dawson James Securities, company reports

Exhibit 2. Income Statement

Can-Fite Biopharma: Income Statement (\$000)																					
YE December 31	2019A	1Q20A	2Q20A	3Q20A	4Q20A	2020A	1Q21E	2Q21E	3Q21E	4Q21E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	
Revenue:	2,032	198	204	211	150	763															
Piclidenoson (CF-101), Rheumatoid Arthritis U.S.												-	-	-	-	-	-	-	-	-	
Piclidenoson (CF-101), Rheumatoid Arthritis EU												-	-	-	-	-	-	-	-	-	
Piclidenoson (CF-101), Psoriasis U.S.												-	-	70,653	147,015	178,446	212,178	248,343	287,085	328,552	
Piclidenoson (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	
Total Product Sales	2,032	198	204	211	150	763	-	-	-	-	-	-	-	124,057	401,170	476,070	556,367	642,375	734,424	832,863	
Milestone From Gebro Holdings																					
Piclidenoson (CF-101), Rheumatoid Arthritis U.S.																					
Royalty Rate from Global Partnership																					
Piclidenoson (CF-101), Rheumatoid Arthritis EU																					
Royalty Rate from Global Partnership																					
Piclidenoson (CF-101), Psoriasis U.S.														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%	
Piclidenoson (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%	
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%	
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%	27%	27%	27%	27%	
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%	
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%	
Total royalties, collaborative revenue																					
Total Revenue	2,032	198	204	211	150	763	-	-	-	-	-	-	-	60,406	157,460	221,311	293,499	344,036	378,360	414,897	
Expenses:																					
Partnership Costs including COGS																					
Research and Development	10,976	3,771	3,283	2,001	2,896	11,951	2,804	2,926	3,169	3,291	12,190	12,434	12,682	12,936	13,195	13,459	13,728	14,003	14,283	14,568	
General and Administrative	3,059	703	752	689	807	2,951	713	744	806	837	3,099	8,000	12,000	12,600	13,230	13,892	14,586	15,315	16,081	16,885	
Total Expenses	14,035	4,474	4,035	2,690	3,703	14,902	3,516	3,669	3,975	4,128	15,289	20,434	24,682	31,739	46,483	51,154	56,132	61,437	67,085	73,097	
Operating Income (Loss)	(12,003)	(4,276)	(3,831)	(2,479)	(3,553)	(14,139)	(3,516)	(3,669)	(3,975)	(4,128)	(15,289)	(20,434)	(24,682)	28,667	110,976	170,157	237,366	282,599	311,276	341,801	
Finance expenses	693																				
Finance income	3,109	(66)	(62)	(96)	(80)	(304)															
Total Other Income	2,416	(66)	(62)	(96)	(80)	(304)															
Pretax Income	(9,587)	(4,342)	(3,769)	(2,383)	(3,473)	(13,835)	(3,516)	(3,669)	(3,975)	(4,128)	(15,289)	(20,434)	(24,682)	28,667	110,976	170,157	237,366	282,599	311,276	341,801	
Taxes on income																					
Adjustments arising from translating financial statements of foreign operations		(715)				(715)								1,433	8,878	20,419	59,342	84,780	99,608	116,212	
Remeasurement loss from defined benefit plans																					
Tax Rate														5%	8%	12%	25%	30%	32%	34%	
GAAP Net Income (Loss)	(9,587)	(4,342)	(3,769)	(2,383)	(3,473)	(14,443)	(3,516)	(3,669)	(3,975)	(4,128)	(15,289)	(20,434)	(24,682)	28,667	110,976	170,157	237,366	282,599	311,276	341,801	
Total comprehensive loss	(9,587)	(5,057)	(3,769)	(2,383)	(3,473)	(15,158)	(3,516)	(3,669)	(3,975)	(4,128)	(15,289)	(20,434)	(24,682)	30,101	102,098	149,739	178,025	197,819	211,667	225,588	
GAAP EPS	(1.77)	(0.47)	(0.25)	(0.16)	(0.14)	(1.02)	(0.14)	(0.10)	(0.11)	(0.09)	(0.45)	(0.41)	(0.49)	0.57	2.19	3.34	4.65	5.51	6.04	6.61	
GAAP EPS (Dil)	(1.35)	(0.31)	(0.13)	(0.08)	(0.08)	(0.49)	(0.08)	(0.06)	(0.07)	(0.06)	(0.26)	(0.26)	(0.31)	0.35	1.37	2.09	2.90	3.44	3.78	4.13	
Wgtd Avg ADR Shrs (Bas) - '000s	5,833	9,222	15,000	15,150	25,165	17,191	25,190	35,000	35,035	45,070	35,074	50,075	50,276	50,477	50,679	50,882	51,086	51,291	51,496	51,703	
Wgtd Avg ADR Shrs (Dil) - '000s	8,910	13,833	30,000	30,300	45,330	29,866	45,376	60,000	60,060	70,120	58,889	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.

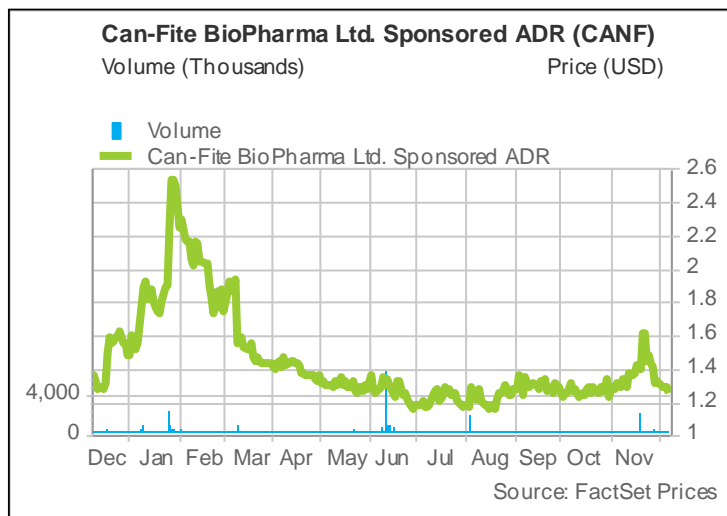
Partnership risk. Can-Fite may seek partnerships for clinical development support and commercialization. We have no specific knowledge of any discussions with possible partners today, and there can be no assurances that the Company will be able to secure a favorable partnership.

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.

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 – January 25, 2021 – Price Target \$5
Update – Buy – February 23, 2021 – Price Target \$5
Update – Buy – March 5, 2021 – Price Target \$5
Update – Buy – March 29, 2021 – Price Target \$5
Update – Buy – April 22, 2021 – Price Target \$5
Update – Buy – April 29, 2021 – Price Target \$5

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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.

As of: 27-Apr-21

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	21	68%	5	24%
Market Perform (Neutral)	10	32%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	31	100%	5	16%

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.