

Can-Fite BioPharma Ltd. (NYSE/CANF)

BUY-Rated – Going Pivotal in Liver Cancer

Can-Fite has received agreement from both the FDA and EMA on the protocol and plans to initiate a pivotal trial for Namodenoson in Liver Cancer, specifically Child-Pugh B7. The trial is planned to be a 450-person global study with a survival endpoint.

July 8, 2021

Jason H. Kolbert

Senior Healthcare Analyst

646-465-6891

jkolbert@dawsonjames.com

Investment Highlights

Namodenoson in Liver Cancer – Pivotal is Next. The FDA and EMA have agreed with Can-Fite's proposed pivotal Phase 3 trial design. Both agencies agreed with Can-Fite's proposed pivotal Phase 3 trial design of Namodenoson for the treatment of patients with advanced hepatocellular carcinoma (HCC), with underlying Child-Pugh B7 (CPB7) cirrhosis to support a New Drug Application (NDA) submission and approval. The trial is expected to enroll 450 patients through multiple centers worldwide. Namodenoson is currently being used to treat liver cancer patients in a compassionate use program in Israel, which has enrolled seven patients (as of 3.2021). 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 four years while being treated with Namodenoson.

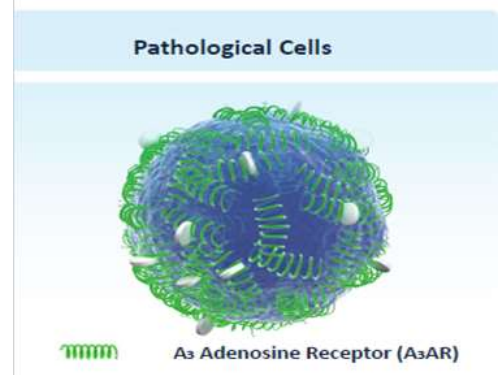
Interim Planned: Can-Fite plans to conduct an interim analysis by an Independent Data Monitoring Committee (IDMC) after 50% of enrolled patients are treated. Namodenoson will be evaluated as a 2nd or 3rd line treatment for CPB7 patients in whom other approved therapies have not been or are no longer effective.

Namodenoson in NAFLD/NASH. Based on positive Phase 2 data last year, we expect to see progression to a Phase 2b trial with liver biopsy as one of the endpoints. Recall that 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%.

Valuation. We evaluate Piclidenoson in Psoriasis but omit 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 use a 30% discount rate, which is also 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.

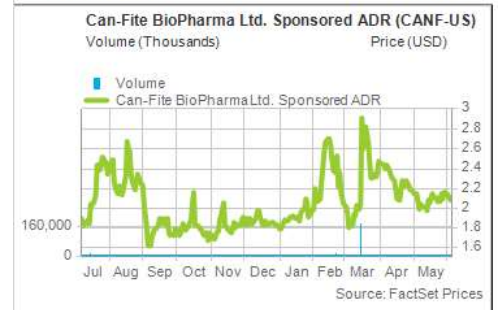
Risks to our thesis include: (1) commercial; (2) regulatory; (3) clinical; (4) financial; (5) partnership; (6) commercial; and (7) legal and intellectual property.

Current Price	\$2.24
Price Target	\$5.00



Source: Can-Fite

Stock Data			
52-Week Range	\$1.51	-	\$4.39
Shares Outstanding (mil.)	17.2		
Market Capitalization (mil.)	\$38.5		
Enterprise Value (mil.)	\$25.5		
Debt to Capital	0.0%		
Book Value/Share	\$4.52		
Price/Book	4.5		
Average Three Months Trading Volume (M)	0.2		
Insider Ownership	1.2%		
Institutional Ownership	8.8%		
Short interest (mil.)	2.0%		
Dividend / Yield	\$0.00/0.0%		



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

Namodenoson - CF102 (US)		2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
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	1,908	2,268	2,643	3,033	3,438
Price of treatment						\$ 50,000	\$ 51,000	\$ 52,020	\$ 53,080	\$ 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	\$ 82,608	\$ 103,135	\$ 125,185	\$ 148,648	\$ 174,220	\$ 201,396
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	\$ 100,699
Namodenoson - CF102 (EU)		2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
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	\$ 103,896	\$ 121,722	\$ 140,911
Namodenoson - CF102 (US)		2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
NAFLD/NASH		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%
Market Penetration								0.25%	0.50%	0.75%	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	\$ 27,602	\$ 28,154
Increase in Price								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)		2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
NAFLD/NASH		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%
Market Penetration								0.00%	0.25%	0.50%	0.75%	1.00%	1.00%	1.00%
Patients receiving CF101								-	33,164	67,954	103,511	140,775	143,590	146,462
Price of treatment								\$ 20,000	\$ 20,400	\$ 20,808	\$ 21,224	\$ 21,649	\$ 22,082	\$ 22,523
Increase in Price								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
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

Source: Dawson James Securities estimates, company reports

Exhibit 2. Income Statement

Can-Fite Biopharma: Income Statement (\$'000)																
: YE December 31																
	2019A	2020A	1Q21A	2Q21E	3Q21E	4Q21E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Revenue:	2,032	763	148				148									
Piclidonoson (CF-101), Rheumatoid Arthritis U.S.								-	-	-	-	-	-	-	-	-
Piclidonoson (CF-101), Rheumatoid Arthritis EU								-	-	-	-	-	-	-	-	-
Piclidonoson (CF-101), Psoriasis U.S.								-	-	70,653	147,015	178,446	212,178	248,343	287,085	328,552
Piclidonoson (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	763	148	-	-	-	148	-	-	124,057	401,170	476,070	556,367	642,375	734,424	832,863
Milestone From Gebro Holdings																
Piclidonoson (CF-101), Rheumatoid Arthritis U.S.																
Royalty Rate from Global Partnership																
Piclidonoson (CF-101), Rheumatoid Arthritis EU																
Royalty Rate from Global Partnership																
Piclidonoson (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%
Piclidonoson (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										60,406	157,460	221,311	293,499	344,036	378,360	414,897
Total Revenue	2,032	763	148	-	-	-	148	-	-	60,406	157,460	221,311	293,499	344,036	378,360	414,897
Expenses:																
Partnership Costs including COGS	-	-	-	-	-	-	-	-	-	6,203	20,059	23,804	27,818	32,119	36,721	41,643
%COGS								5%	5%	5%	5%	5%	5%	5%	5%	5%
Research and Development	10,976	11,951	1,303	2,000	2,000	2,000	7,303	7,449	7,598	7,750	7,905	8,063	8,224	8,389	8,557	8,728
%R&D																
General and Administrative	3,059	2,951	1,016	1,000	1,000	1,000	4,016	8,000	12,000	12,600	13,230	13,892	14,586	15,315	16,081	16,885
%SG&A																
Total Expenses	14,035	14,902	2,319	3,000	3,000	3,000	11,319	15,449	19,598	26,553	41,194	45,758	50,629	55,823	61,359	67,256
Operating Income (Loss)	(12,003)	(14,139)	(2,171)	(3,000)	(3,000)	(3,000)	(11,171)	(15,449)	(19,598)	33,853	116,266	175,553	242,870	288,213	317,001	347,641
Finance expenses	693															
Finance income	3,109	(304)	293				293									
Total Other Income	2,416	(304)	293	-	-	-	293	-	-	-	-	-	-	-	-	-
Pretax Income	(9,587)	(13,835)	(1,878)	(3,000)	(3,000)	(3,000)	(11,464)	(15,449)	(19,598)	33,853	116,266	175,553	242,870	288,213	317,001	347,641
Taxes on income																
Adjustments arising from translating financial statements of foreign operations		(715)								1,693	9,301	21,066	60,717	86,464	101,440	118,198
Remeasurement loss from defined benefit plans																
Tax Rate										5%	8%	12%	25%	30%	32%	34%
GAAP Net Income (Loss)	(9,587)	(14,443)	(1,878)	(3,000)	(3,000)	(3,000)	(11,464)	(15,449)	(19,598)	33,853	116,266	175,553	242,870	288,213	317,001	347,641
Total comprehensive loss	(9,587)	(15,158)	(1,878)	(3,000)	(3,000)	(3,000)	(11,464)	(15,449)	(19,598)	35,546	106,965	154,487	182,152	201,749	215,561	229,443
GAAP-EPS	(1.77)	(1.02)	(0.11)	(0.09)	(0.09)	(0.07)	(0.35)	(0.31)	(0.39)	0.67	2.29	3.45	4.75	5.62	6.16	6.72
GAAP-EPS (Dil)	(1.35)	(0.48)	(0.06)	(0.05)	(0.05)	(0.04)	(0.21)	(0.19)	(0.24)	0.42	1.43	2.16	2.97	3.51	3.85	4.20
Wgtd Avg ADR Shrs (Bas) - '000s	5,833	17,191	17,191	35,000	35,035	45,070	33,074	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	29,866	29,866	60,000	60,060	70,120	55,011	80,120	80,441	80,763	81,087	81,412	81,738	82,065	82,394	82,724

Source: Dawson James Securities estimates, 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.

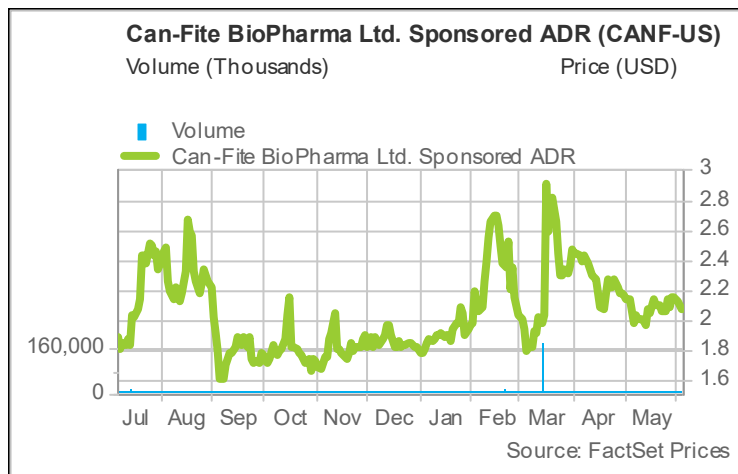
Partnership risk. Can-Fite may seek partnerships for clinical development support and commercialization. We have no specific knowledge of any discussions with possible partners today, and there can be no assurances that the Company will be able to secure a favorable partnership.

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
Update – Buy – May 27, 2021 – Price Target \$5
Update – Buy – June 4, 2021 – Price Target \$5
Update – Buy – July 8, 2021 – Price Target \$5

Dawson James Securities, Inc. (the "Firm") is a member of the Financial Industry Regulatory Authority ("FINRA") and the Securities Investor Protection Corporation ("SIPC").

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.

Neither the research analyst(s) whose name appears on this report nor any member of his (their) household is an officer, director or advisory board member of these companies. The Firm and/or its directors and employees may own securities of the Company (s) in this report and may increase or decrease holdings in the future. As of June 30, 2021, the Firm as a whole did not beneficially own 1% or more of any class of common equity securities of the subject company(s) of this report. The Firm, its officers, directors, analysts or employees may affect transactions in and have long or short positions in the securities (or options or warrants related to those securities) of the Company (s) subject to this report. The Firm may affect transactions as principal or agent in those securities.

Analysts receive no direct compensation in connection with the Firm's investment banking business. All Firm employees, including the analyst(s) responsible for preparing this report, may be eligible to receive non-product or service-specific monetary bonus compensation that is based upon various factors, including total revenues of the Firm 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.

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.

The securities of the Company discussed in this report may be unsuitable for investors depending on their specific investment objectives and financial position. This report is offered for informational purposes only and does not constitute an offer or solicitation to buy or sell any securities discussed herein in any jurisdiction where such would be prohibited. Additional information is available upon request.

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: 30-Jun-21

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	24	71%	4	17%
Market Perform (Neutral)	10	29%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	34	100%	4	12%

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.