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Mesoblast (NASDAQ/MESO, ASX/MSB)

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BUY: DDD Results Look Good – Approval Could Follow Now

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Mesoblast reports positive results from the degenerative disc disease trial. The data shows that a that injection of rexlemestrol-L appears to provide durable and effective opioid sparing therapy for patients with chronic inflammatory back pain due to degenerative disc disease. Relief appears to be durable for two years-plus from a single administration.

Investment Highlights:

A New Treatment Paradigm in Back Pain – Moving Beyond Steroids and Opiates. From the time man crawled out of the primordial ooze and stood upright as a biped, back pain followed. Chronic lower back pain (CLBP) likely results in more disabilities than just about any other condition. With the recognition of the hazards of prescribing opiates to treat pain (the symptom), versus addressing the underlying cause, such as a herniated disc and in its final stages, spinal fusion (surgery), a new modality is needed. Mesoblast’s CLBP hopes to be part of the solution, literally swapping cells for steroids for injection into the intra-vertebral space, supporting repair of the underlying cause, disc herniation, and the resulting inflammation.

Trial Data: A single injection of MPC + Hyaluronic Acid (HA) carrier resulted in:

- Achievement of significant and durable reductions in CLBP through 24 months across the entire evaluable study population (n=391) compared with saline controls.
- Greatest pain reduction observed in the pre-specified population with CLBP of shorter duration than the study median of 68 months (n=194), significantly greater reduction at all time points (1, 3, 6, 12, 18 and 24 months) compared with saline controls.
- Significantly greater pain reduction in the pre-specified patient subset of opioid users (n=168) at all time-points compared with saline controls.
- Confirmation of durable pain reduction seen with the combination of rexlemestrol-L + HA in the previous randomized controlled trial, where HA control alone was not significantly different from saline.
- Increased composite outcomes of reduction in pain together with improvement in function in those with CLBP of shorter duration than 68 months, the median for the study; however, the composite outcomes of pain and function did not reach statistical significance across the entire study.
- No safety concerns over the 24-month period of follow-up in the entire study population.

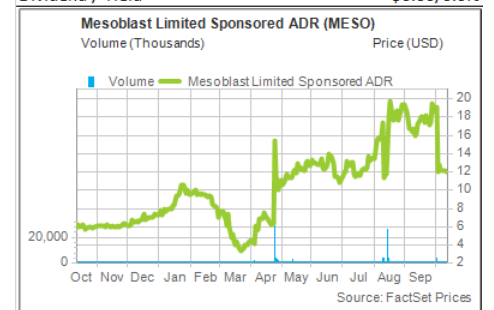
Mesoblast plans to meet with the FDA to discuss the results from this trial together with the earlier randomized controlled trial of MPC + HA, and potential approval pathways for rexlemestrol-L + HA as treatment for durable reduction in CLBP due to DDD with opioid sparing activity.

Risks to our thesis include the following: (1) clinical and regulatory; (2) commercial; (3) employee; (4) financial; (5) legal and intellectual property; and (6) partnership. We review these and other risks in the risk section of this report.

Current Price	\$12.01		
Price Target	\$16.00		
Estimates	F2019A	F2020E	F2021E
Expenses (\$000s)	\$ 97	\$ 92	\$ 136
1Q March	\$ 28	\$ 28	\$ 31
2Q June	\$ 27	\$ 22	\$ 33
3Q September	\$ 23	\$ 23	\$ 34
4Q December	\$ 19	\$ 19	\$ 38
	F2019A	F2020E	F2021E
EPS (diluted)	\$ (0.72)	\$ (0.63)	\$ (0.62)
1Q March	\$ (0.19)	\$ (0.14)	\$ (0.14)
2Q June	\$ (0.05)	\$ (0.17)	\$ (0.15)
3Q September	\$ (0.20)	\$ (0.18)	\$ (0.15)
4Q December	\$ (0.28)	\$ (0.14)	\$ (0.17)

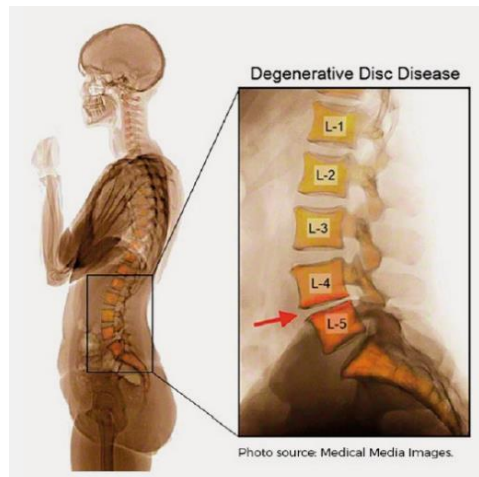
EBITDA/Share	(\$0.90)	(\$0.53)	(\$0.61)
EV/EBITDA (x)	-13.6	-19.2	-16.6

Stock Data			
52-Week Range	\$3.12	-	\$21.28
Shares Outstanding (mil.)	117.3		
Market Capitalization (mil.)	\$1,409		
Enterprise Value (mil.)	\$1,438		
Debt to Capital	6%		
Book Value/Share	\$6.02		
Price/Book	2.4		
Average Three Months Trading Volume (K)	290		
Insider Ownership	21.0%		
Institutional Ownership	26.7%		
Short interest (mil.)	2.7%		
Dividend / Yield	\$0.00/0.0%		



Chronic Lower Back Pain (CLBP) is most commonly caused by disruption to the discs found in between vertebrae. These fluid-filled discs give people movement and stability in their everyday lives. When the nerves surrounding these discs are damaged, causing an inflammatory response, it causes chronic pain and functional disability. This damage can be caused by trauma, genetic predisposition, or aging and affects more than 3.2 million people in the United States alone.

Exhibit 1. The Effect of Degenerative Disc Disease on Spinal Vertebrae



The Current Standard of Care for CLBP focuses on masking the pain rather than treating the problem at its core. All treatment options provide patients with short term solutions to their pain with the intention of temporarily minimizing it. Ibuprofen is a common relief to this problem, with more extreme solutions being major back surgery for long term management. Opioids are commonly prescribed in order to relieve the pain associated with degenerative disc disease. In fact, more than half of the prescriptions for opioids are for people with this condition. Opioids have recently been declared a public health emergency due to their addictive qualities, leading to the need for a non-addictive solution.

MPC-06-ID is a Phase 3 drug intended for the treatment of CLBP due to disc degeneration. The product will be injected directly into the patient's damaged disc, using only 6 MPCs. MPC-06-ID will act as an anti-inflammatory, triggering the creation of new proteoglycan and collagen in order to regenerate the disc. Therefore, this drug does not aim to simply cover the pain, but rather, strengthen the disc in order to resolve the problem at its core.

Phase 3 Trial. Mesoblast has now completed and reported the Phase 3 trial data. The trial evaluated over 400 patients with CLBP due to disc degeneration. The primary endpoints is pain relief, as measured by a 50% reduction in lower back pain. While seemingly subjective, these factors would be measured using Visual Analog Score and a 15-point improvement in the Oswestry Disability Index, ensuring the objective nature of the data. Overall Treatment Success Composites has been measured at 12 months and 24 months, with no additional treatments over the course of time. See front page for the results.

Phase 2 Trial. The Phase 2 trial of MPC-06-ID had several primary endpoints: efficacy, medication usage, and quality of life improvement measures. There were 100 patients enrolled; each suffered from CLBP due to disc degeneration for at least sixth months prior to the trial. After the injection of MPC-06-ID, patients saw statistically significant improvements in pain and function up to three years after.

Modeling Assumptions for Degenerative Disc Disease (DDD)

1. We assume market share penetration for Back Pain & Related Disc Repair to be 5% in 2023 and increase to 24% in 2030.
2. We assume that the market size will increase by 0.5% annually.
3. We assume the probability of success for all CLBP patients to be 50%.
4. We assume the cost of therapy to be \$10,040 in 2018 and grow 0.2% each year to reach \$10,284 in 2030.

Exhibit 2. DDD Model. We apply a 50% risk cut to the model below.

Back Pain & Related Disc Repair	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Back Pain Prevalance	30,452,254	30,604,515	30,757,538	30,911,325	31,065,882	31,221,211	31,377,317	31,534,204	31,691,875	31,850,334	32,009,586	32,169,634	32,330,482
Market Size Growth (Annual)	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%
5% Patients Considered Candidates for Therapy	1,522,613	1,530,226	1,537,877	1,545,566	1,553,294	1,561,061	1,568,866	1,576,710	1,584,594	1,592,517	1,600,479	1,608,482	1,616,524
Patients which qualify	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%
Target Market	380,653	382,556	384,469	386,392	388,324	390,265	392,216	394,178	396,148	398,129	400,120	402,120	404,131
Market Share Penetration	0.0%	0.0%	0.0%	0.0%	0.0%	5.0%	10.0%	15.0%	20.0%	22.0%	24.0%	24.0%	24.0%
Number of Patients Procedures	0	0	0	0	0	19,513	39,222	59,127	79,230	87,588	96,029	96,509	96,991
Cost of Therapy \$	10,040	10,060	10,080	10,100	10,121	10,141	10,161	10,181	10,202	10,222	10,243	10,263	10,284
Price Growth	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
Probability of Success	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
U.S. Annual Sales (M) \$	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 99	\$ 199	\$ 301	\$ 404	\$ 448	\$ 492	\$ 499

Source: Dawson James estimates

Valuation: Our valuation methodology begins with our projected revenues from our product models, which are adjusted by a “probability of success or risk factor.” We apply assumptions for the timing of approval, launch dates, and product attributes to estimate revenues. These estimates feed into our income statement through the year 2030. The result of these projections is then fed into our income statement projections. Our price target is derived from an equal-weighted average of free cash flow to the firm (FCFF), discounted EPS (EPS), and sum-of-the-parts (SOP) models. A 30% discount is then applied and rounded to the nearest whole number to derive our price target. A higher risk rate of 30% is applied (vs. 15% or 10%) since Mesoblast is a microcap company with drug candidates in clinical trials that have yet to gain FDA approval.

Exhibit 3. Free Cash Flow Model

Average \$	16
Price Target \$	16
Year	2021

DCF Valuation Using FCF (mln):

units (millions - \$)	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(75)	(117)	(122)	21	390	921	2,070	2,901	3,634	3,664	3,692
Tax Rate	3%	0%	0%	15%	25%	30%	35%	36%	36%	36%	36%
EBIT(1-t)	(73)	(117)	(122)	18	293	645	1,345	1,857	2,326	2,345	2,363
CapEx											
Depreciation											
Change in NWC											
FCF	(73)	(117)	(122)	18	293	645	1,345	1,857	2,326	2,345	2,363
PV of FCF	(95)	(117)	(94)	11	133	226	362	385	371	287	223
Discount Rate		30%									
Long Term Growth Rate		1%									
Free Cash Flow		8,229									
Terminal Value YE 2030		776									
NPV		2,469									
NPV-Debt		84									
Shares out (M)		146	2030E								
NPV Per Share	\$	16									

Source: Dawson James estimates, company reports

Exhibit 4. Discounted-EPS Model

Year of EPS	2021
Earnings Multiple	10
Discount Factor	30%
Selected Year EPS	\$ 16.20
NPV	\$ 15

		Discount Rate and Earnings Multiple Varies, Year is Constant					
		2030 EPS					
		10%	15%	20%	25%	30%	35%
Earnings Multiple	1	\$6.87	\$4.60	\$3.14	\$2.17	\$1.53	\$ 1.09
	5	\$34.34	\$23.02	\$15.69	\$10.87	\$7.64	\$ 5.44
	10	\$68.69	\$46.04	\$31.39	\$21.74	\$15.27	\$ 10.87
	15	\$103.03	\$69.06	\$47.08	\$32.61	\$22.91	\$ 16.31
	20	\$137.38	\$92.08	\$62.78	\$43.48	\$30.55	\$ 21.75
	25	\$171.72	\$115.10	\$78.47	\$54.35	\$38.18	\$ 27.19
	30	\$206.06	\$138.12	\$94.17	\$65.22	\$45.82	\$ 32.62
	35	\$240.41	\$161.14	\$109.86	\$76.08	\$53.46	\$ 38.06

Source: Dawson James estimates

Exhibit 5. Sum-of-the-Parts Model

Mesoblast Sum of the Parts	LT Gr	Discount Rate	Yrs. to Mkt	% Success	Peak Sales MM's	NPV
Revascor - CHF (Class II - III) U.S.	1%	30%	4	25%	\$5,152	\$17,766
NPV						\$5.33
Revascor - CHF - LVAD: Class IV	1%	30%	2	25%	\$361	\$1,246
NPV						\$0.63
Revascor - CHF (Class II - III) EU	1%	30%	5	25%	\$3,895	\$13,431
NPV						\$3.10
Acute Pediatric GvHD - U.S.	1%	30%	0	100%	\$142	\$490
NPV						\$1.68
Acute Adult GvHD U.S.	1%	30%	4	100%	\$319	\$1,101
NPV						\$1.32
Acute Pediatric GvHD - E.U.	1%	30%	3	100%	\$101	\$350
NPV						\$0.55
Acute Adult GvHD E.U.	1%	30%	3	100%	\$383	\$1,322
NPV						\$2.06
CLBD-DDD U.S.	1%	30%	2	30%	\$984	\$3,392
NPV						\$2.06
TEMCELL	1%	10%	0	75%	\$20	\$222
NPV						\$0.57
Other Indications	1%	30%	5	30%	\$0	\$0
NPV						\$0.00
Net Margin						50%
MM.Shrs OS					2030E	146
Total						\$17

Source: Dawson James estimates

Exhibit 6. Income Statement

Mesoblast, Inc. Income Statement (M)	Sept.	Dec.	March	June												
Mesoblast: YE June 30	2019A	1Q20A	2Q20	3Q20	4Q20	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Milestone / Partnership Revenues	14	12														
% Sequential Growth																
Revascor in CHF U.S.	-	-	-	-	-	-	-	-	-	255	638	1,280	1,926	2,576	2,584	2,592
% Sequential Growth																
Revascor in CHF; EU	-	-	-	-	-	-	-	-	-	-	-	830	1,387	1,948	1,953	1,959
% Sequential Growth																
Disogenic Disc Chronic Lower Back (U.S.)									139	279	421	566	627	689	693	698
% Sequential Growth																
Remestemcel-L GvHD - USA - Pediatric	1						43	87	132	145	141	137	139	142	145	148
% Sequential Growth																
Remestemcel-L GvHD - USA - Acute Adult	-	-	-	-	-	-	-	-	-	102	198	288	313	319	326	332
% Sequential Growth																
Remestemcel-L GvHD - EU Pediatric	-	-	-	-	-	-	-	27	67	110	107	104	106	108	110	110
% Sequential Growth																
Remestemcel-L GvHD - EU Acute Adult	-	-	-	-	-	-	-	-	-	-	119	230	352	383	391	399
% Sequential Growth																
Product Revenues	15	12	-	-	-	12	43	114	338	891	1,624	3,434	4,850	6,164	6,202	6,238
TemCell GvHD - Japan Adult & Pediatric	1	2	2	2	2	7	7	9	11	12	13	14	16	17	18	19
Product & Royalty Revenues	17	17	2	2	2	22	50	123	349	903	1,638	3,448	4,866	6,181	6,220	6,257
Expenses																
MesoBlast COGS	-					-	13	23	68	134	227	343	485	616	620	624
COGS % Sales	0%	0%	0%	0%	0%	0%	30%	-20%	-20%	-15%	-14%	-10%	-10%	-10%	-10%	-10%
R&D	60	14	15	16	18	63	66	69	73	76	73	69	65	66	67	67
Manufacturing & Commercialization	15	8	4	4	1	16	32	26	21	20	19	18	18	17	16	16
Management & Administration	22	6	3	3	1	13	25	36	37	39	38	38	37	36	35	35
Total expenses	97	28	22	23	19	92	136	153	198	269	357	468	605	736	739	741
Oper. Inc. (Loss)	(80)	(11)	(20)	(21)	(17)	(70)	(87)	(31)	151	634	1,280	2,980	4,261	5,446	5,481	5,515
Oper Margin																
Fair Value Remeasurement (contingent consideration)	(6)	2														
Finance Cost/Interest Expense		3														
Changes in the fair value of available-for-sale financial assets																
Exchange differences on translation of foreign operations	(1)															
Interest Payments	(11)	(0)	-	-	-	(0)	-	-	-	-	-	-	-	-	-	-
Other comprehensive loss/income for the period, net of tax	(20)	5	-	-	-	5	-	-	-	-	-	-	-	-	-	-
Pre-tax income	(105)	(16)	(20)	(21)	(17)	(75)	(87)	(31)	151	634	1,280	2,980	4,261	5,446	5,481	5,515
Pretax Margin																
Tax benefit (or expense)	9	2	-	-	-	2	-	-	(23)	(158)	(384)	(1,043)	(1,534)	(1,960)	(1,973)	(1,986)
Tax Rate		0%	0%	0%	0%	3%	0%	0%	15%	25%	30%	35%	36%	36%	36%	36%
Net income	(97)	(15)	(20)	(21)	(17)	(73)	(87)	(31)	128	475	896	1,937	2,727	3,485	3,508	3,530
Net Margin																
EPS	\$ (0.72)	\$ (0.14)	\$ (0.17)	\$ (0.18)	\$ (0.14)	\$ (0.63)	\$ (0.62)	\$ (0.22)	\$ 0.90	\$ 3.34	\$ 6.27	\$ 13.49	\$ 18.92	\$ 24.08	\$ 24.14	\$ 24.20
Non GAAP EPS (dil)																
Wgt'd Avg Shrs (Bas) - '000s	106	108	120	120	120	117	141	141	142	142	143	144	144	145	145	146
Wgt'd Avg Shrs (Dil) - '000s	106	108	120	120	120	117	141	141	142	142	143	144	144	145	145	146

Source: Dawson James estimates, company reports

Risk Analysis

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

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

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.

Employee risk. Mesoblast has an experienced and dedicated management team, many of whom have been with the company since its founding. The company plans to bring its proposed products to market in the next two years, and as such, transitioning from a clinical to a commercial team will be a critical success factor. The success of the business may depend on the experience, abilities, and continued services of its senior officers, sales staff, and key scientific personnel.

Financial risk. The company may need to raise capital in the marketplace in order to support operations. There are no assurances that the company will be able to successfully raise capital and or do so on favorable terms.

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.

Partnership risk. Mesoblast 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.

Important Disclosures:

Companies that May Be Mentioned in this report which Mesoblast has worked with or which may be relative to Mesoblast include the list below. None of these companies are rated.

BlueBird

Cephalon

Grunenthal

JCR Pharma

Juno

Kite

Lonza

Novartis

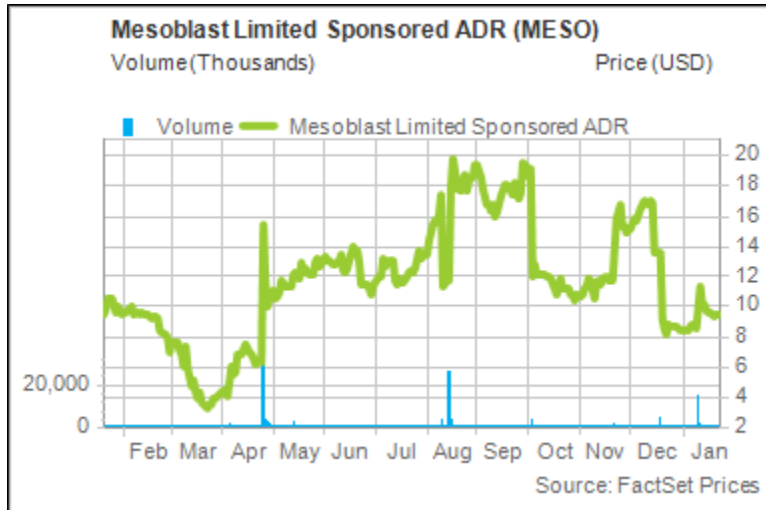
Osiris

Takeda (which acquired Tigenix)

Teva

Tasly

Price Chart:



Price target and rating changes over the past three years:

- Initiated – Buy – December 19, 2019 – Price Target \$14.00
- Update – Buy – January 16, 2020 – Price Target \$14.00
- Update – Buy – January 28, 2020 – Price Target \$15.00
- Update – Buy – February 3, 2020 – Price Target \$15.00
- Update – Buy – February 28, 2020 – Price Target \$15.00
- Update – Buy – March 10, 2020 – Price Target \$15.00
- Update – Buy – April 1, 2020 – Price Target \$15.00
- Update – Buy – April 6, 2020 – Price Target \$15.00
- Update – Buy – April 17, 2020 – Price Target \$15.00
- Update – Buy – April 24, 2020 – Price Target \$15.00
- Update – Buy – May 1, 2020 – Price Target \$15.00
- Update – Buy – May 6, 2020 – Price Target \$15.00
- Update – Buy – May 26, 2020 – Price Target \$15.00
- Update – Buy – May 28, 2020 – Price Target \$15.00
- Update – Buy – July 30, 2020 – Price Target \$15.00
- Price Target Change – Buy – August 24, 2020 – Price Target Increased to \$20.00 from \$15.00
- Update – Buy – September 2, 2020 – Price Target \$20.00
- Update – Buy – October 2, 2020 – Price Target \$20.00
- Update – Buy – October 13, 2020 – Price Target \$20.00
- Update – Buy – November 20, 2020 – Price Target \$20.00
- Update – Buy – December 8, 2020 – Price Target \$20.00
- Update – Buy – December 15, 2020 – Price Target \$20.00
- Update – Buy – December 18, 2020 – Price Target \$20.00
- Price Target Change – Buy – January 22, 2021 – Price Target lowered to \$16.00 from \$20.00
- Update – Buy – February 11, 2021 – Price Target \$16.00

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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.

Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	21	72%	5	24%
Market Perform (Neutral)	8	28%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	29	100%	5	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.