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Mesoblast (NASDAQ/MESO, ASX/MSB)

January 22, 2021

BUY: Yes…DDD Results are Ahead – What's Priced In?

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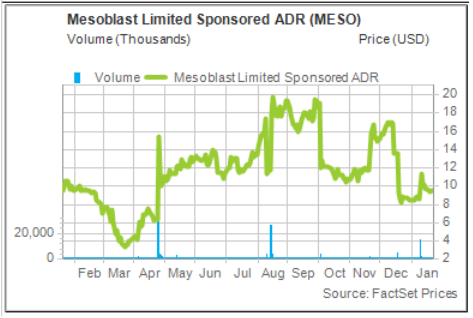
The key question is, do you believe that Regenerative Medicine works? If so, can a recent string of technical trial misses (narrow failures to achieve p-values on the primary endpoint) be explained by adjusting our understanding of which patients benefit the most from cell therapy? We think so, yes. We strongly believe that Mesoblast's Revascor is a viable heart failure therapy and that remestemcel has efficacy in GvHD. So, what's next? The Degenerative Disc Disease (DDD) trial. We view the outcome of this trial as very tough to predict, and in fact, have a negative bias. The challenge is for cells to work in what we consider to be a hostile environment, the intervertebral space. Expectations are low, and failure appears to be "mostly" priced into the stock. We adjust our probability of success down to 50% in our revenue model, which drives a price target reduction from $20.00 to $16.00.

Current Price	**$9.48**
Price Target	**$16.00**

Estimates	F2019A	F2020E	F2021E
Expenses ($000s)	$ 97	$ 92	$ 124
1Q March	$ 28	$ 28	$ 28
2Q June	$ 27	$ 22	$ 30
3Q September	$ 23	$ 23	$ 31
4Q December	$ 19	$ 19	$ 35
	F2019A	F2020E	F2021E
EPS (diluted)	$ (0.72)	$ (0.63)	$ (0.83)
1Q March	$ (0.19)	$ (0.14)	$ (0.19)
2Q June	$ (0.05)	$ (0.17)	$ (0.20)
3Q September	$ (0.20)	$ (0.18)	$ (0.21)
4Q December	$ (0.28)	$ (0.14)	$ (0.23)
EBITDA/Share	($0.90)	($0.53)	($0.83)
EV/EBITDA (x)	-10.8	-15.3	-9.8
Stock Data			
52-Week Range	$3.12	-	$21.28
Shares Outstanding (mil.)			117.3
Market Capitalization (mil.)			$1,112
Enterprise Value (mil.)			$1,141
Debt to Capital			7%
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%



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.

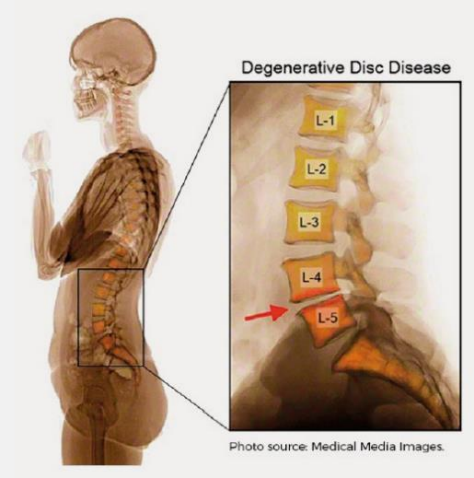
The Heart Failure Trial. Top-line data from the Phase 3 trial of Revascor in Congestive Heart Failure Patients showed that over a mean 30 months of follow-up, patients with advanced chronic heart failure who received a single endomyocardial treatment with rexlemestrocel-L on top of maximal therapies had 60% reduction in incidence of heart attacks or strokes and 60% reduction in death from cardiac causes when treated at an earlier stage in the progressive disease process. Unfortunately, and despite the significant reduction in the pre-specified endpoint of cardiac death, there was no reduction in recurrent non-fatal decompensated heart failure events, which was the trial's primary endpoint.

GvHD Trial. Back in October, Mesoblast received a Complete Response Letter (CRL) regarding the Biologics License Application (BLA) for remestemcel-L for the treatment of pediatric steroid-refractory acute graft versus host disease (SR-aGVHD). On the surface, this is surprising given the Oncologic Drugs Advisory Committee (ODAC) voted 9:1 that the available data support the efficacy of remestemcel-L in pediatric patients with SR-aGVHD. So, what happens now? The FDA wants one additional randomized, controlled study in adults and children to provide further evidence of the effectiveness of remestemcel-L. Still, given the lack of approved treatments for this life-threatening condition in children under 12, Mesoblast plans to seek an accelerated approval with a post-approval condition that could satisfy regulators.

Risk 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.

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 completed enrollment for the pivotal (Phase 3 trial). The trial is evaluating n~ 404 patients with CLBP due to disc degeneration. The primary endpoints would be pain relief as well as 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 will be measured both at 12 months and 24 months, with no additional treatments over the course of time.

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	$ 495	$ 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

		2021
Year of EPS		2030
Earnings Multiple		10
Discount Factor		30%
Selected Year EPS	$	16.20
NPV	$	15

	Discount Rate and Earnings Multiple Varies, Year is Constant 2030 EPS					
Earnings Multiple	10%	15%	20%	25%	30%	35%
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)												
Mesoblast: YE June 30	**2019A**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**	**2029E**	**2030E**
Milestone / Partnership Revenues	14											
% Sequential Growth												
Revasco in CHF U.S.		-	-	-	-	153	383	768	1,156	1,546	1,550	1,555
% Sequential Growth												
Revascor in CHF; EU	-	-	-	-	-	-	-	498	832	1,169	1,172	1,176
% Sequential Growth												
Discogenic Disc Chronic Lower Back (U.S.)			-	-	99	199	301	404	448	492	495	499
% Sequential Growth												
Remestemcel-L GvHD - USA - Pediatric	1	-	-	-	44	86	124	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	-	-	-	-	33	65	82	98	99	101	104	104
% Sequential Growth												
Remestemcel-L GvHD - EU Acute Adult	-	-	-	-	-	-	119	230	352	383	391	399
% Sequential Growth												
Product Revenues	**15**	**12**	**-**	**-**	**177**	**605**	**1,207**	**2,422**	**3,340**	**4,152**	**4,183**	**4,211**
TemCell GvHD - Japan Adult & Pediatric	1	7	7	9	11	12	13	14	16	17	18	19
Product & Royalty Revnues	**17**	**22**	**7**	**9**	**187**	**616**	**1,220**	**2,437**	**3,355**	**4,169**	**4,200**	**4,231**
Expenses												
MesoBlast COGS	-	-	-	-	35	91	169	242	334	415	418	421
COGS % Sales	0%	0%			-20%	-15%	-14%	-10%	-10%	-10%	-10%	-10%
R&D	60	63	66	69	73	76	73	69	65	66	67	67
Manufacturing & Commercialization	15	16	32	26	21	20	19	18	18	17	16	16
Management & Adminastration	22	13	25	36	37	39	38	38	37	36	35	35
Total expenses	**97**	**92**	**124**	**131**	**166**	**226**	**299**	**367**	**454**	**534**	**537**	**539**
Oper. Inc. (Loss)	(80)	(70)	(117)	(122)	21	390	921	2,070	2,901	3,634	3,664	3,692
Oper Margin												
Fair Value Remeasurement (contingent consideration)	(6)											
Finance Cost/Interest Expense												
Changes in the fair value of available-for-sale financial assets												
Exchange differences on translation of foreign operations	(1)											
Interest Payments	(11)	(0)	-			-	-	-	-	-	-	-
Other comprehensive loss/income for the period, net of tax												
Total other income	(20)	5	-	-	-	-	-	-	-	-	-	-
Pre-tax income	**(105)**	**(75)**	**(117)**	**(122)**	**21**	**390**	**921**	**2,070**	**2,901**	**3,634**	**3,664**	**3,692**
Pretax Margin												
Tax benefit (or expense)	9	2	-	-	(3)	(98)	(276)	(724)	(1,044)	(1,308)	(1,319)	(1,329)
Tax Rate		3%	0%	0%	15%	25%	30%	35%	36%	36%	36%	36%
Net Income	**(97)**	**(73)**	**(117)**	**(122)**	**18**	**293**	**645**	**1,345**	**1,857**	**2,326**	**2,345**	**2,363**
Net Margin												
EPS	**$ (0.72)**	**$ (0.63)**	**$ (0.83)**	**$ (0.86)**	**$ 0.13**	**$ 2.05**	**$ 4.51**	**$ 9.37**	**$ 12.88**	**$ 16.07**	**$ 16.14**	**$ 16.20**
Non GAAP EPS (dil)												
Wgtd Avg Shrs (Bas) - '000s	106	117	141	141	142	142	143	144	144	145	145	146
Wgtd Avg Shrs (Dil) - '000s	106	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.

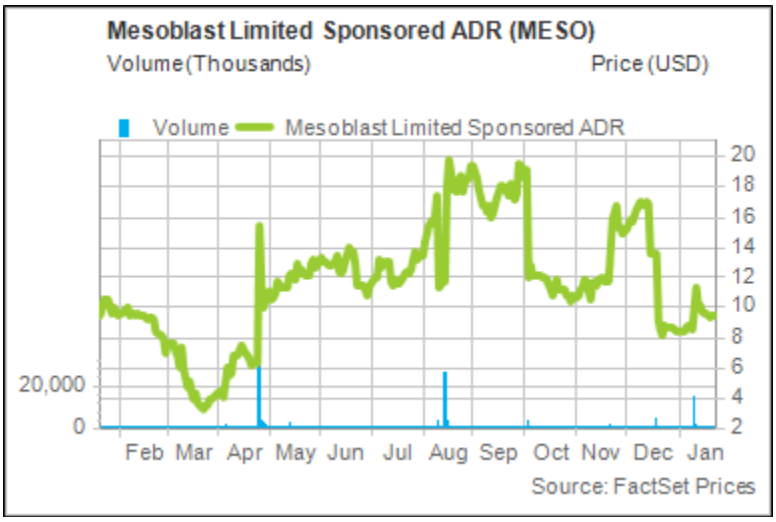
Financial risk. The company may need to raise capital in the marketplace in order to support operations. There are no assurances that the company will be able to successfully raise capital and or do so on favorable terms.

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
Grunethal
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

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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.

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	22	79%	2	9%
Market Perform (Neutral)	6	21%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	28	100%	2	7%

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.