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UPDATE REPORT

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Mesoblast (NASDAQ/MESO, ASX/MSB)

July 1, 2021

BUY: Regulatory Path for Degenerative Disc Disease

Jason Kolbert
Senior Healthcare Analyst
jkolbert@dawsonjames.com

Mesoblast has filed a request and expects to hold a Type C meeting with the US Food & Drug Administration (FDA) during the current quarter to discuss the pathway to US regulatory approval for rexlemestrocel-L following the recently completed 404-patient Phase 3 trial in patients with chronic inflammatory back pain due to degenerative disc disease.

Investment Highlights:

Type C Meeting Requested: Mesoblast has filed a request and expects to hold a Type C meeting with the FDA to discuss the pathway to U.S. regulatory approval for rexlemestrocel-L following the recently completed n=404 patient Phase 3 trial in patients with chronic inflammatory back pain due to degenerative disc disease. A Type C meeting is basically a "catch all" category and includes any meeting concerning the development and review of a product that does not fall within the scope of Types A or B. The FDA notes that it will attempt to schedule all Type C meetings within 75 days of receiving the written meeting request.

What's the Plan? To leverage the results from a planned U.S. trial to support product approvals in the U.S. and EU by including 20% EU patients in order to provide regulatory harmonization, cost efficiencies and streamlined timelines without initiating an EU trial. In line with this strategy, Mesoblast and its partner in Europe and Latin America, Grünenthal, have amended their collaboration agreement, with Mesoblast being eligible to receive payments up to US$112.5 million prior to product launch in the EU, inclusive of US$17.5 million already received, if certain clinical and regulatory milestones are satisfied and reimbursement targets are achieved. Cumulative milestone payments could reach $1 billion depending on the final outcome of Phase 3 studies and patient adoption. Mesoblast will also receive tiered double-digit royalties on product sales as per the original agreement.

Recent Update Reminder: Mesoblast announced results for the period ending March 31, 2021. The company closed the period with a cash balance of $158M. Multiple partners including Novartis are now working with the company to achieve a transition (pending approval) to commercialization. The next two quarters have the potential to be transformative for the company.

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.

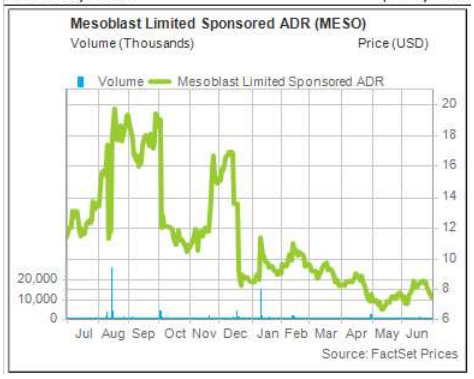
Risks to our thesis include: (1) clinical and regulatory; (2) commercial; (3) employee; (4) financial; (5) legal and intellectual property; and (6) partnership.

Current Price	**$7.28**
Price Target	**$16.00**

Mesoblast's portfolio of Phase 3 product candidates are:

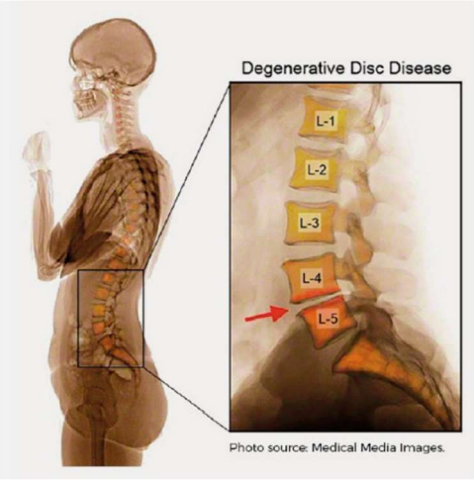
- Remestemcel-L for steroid-refractory acute graft versus host disease (acute GVHD) in children
- Remestemcel-L for moderate to severe acute respiratory distress syndrome (ARDS) due to COVID-19 infection
- REVASCOR® for advanced chronic heart failure
- MPC-06-ID for chronic low back pain due to degenerative disc disease

52-Week Range	$7.22	-	$21.28
Shares Outstanding (mil.)			129.7
Market Capitalization (mil.)			$945
Enterprise Value (mil.)			$973
Book Value/Share			$6.02
Price/Book			2.4
Average Three Months Trading Volume (K)			446
Insider Ownership			13.2%
Institutional Ownership			24.6%
Short interest (mil.)			1.0%
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



Source: Mesoblast

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	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%
U.S. Annual Sales (M)	$ -	$ -	$ -	$ -	$ -	$ 139	$ 279	$ 421	$ 566	$ 627	$ 689	$ 693	$ 698

Source: Dawson James estimates

Exhibit 3. Income Statement (not updated)

Mesoblast, Inc. Income Statement (M)																
Mesoblast: YE June 30	**2019A**	**2020E**	**1Q21**	**2Q21**	**3Q21**	**4Q21**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**	**2029E**	**2030E**
Milestone / Partnership Revenues	14															
% Sequential Growth																
Revasco 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																
Discogenic Disc Chronic Lower Back (U.S.)			-	-	-	-	-	-	139	279	421	566	627	689	693	698
% Sequential Growth																
Remestemcel-L GvHD - USA - Pediatric	1	-	10	10	11	12	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**	**10**	**10**	**11**	**12**	**43**	**114**	**338**	**891**	**1,624**	**3,434**	**4,850**	**6,164**	**6,202**	**6,238**
TemCell GvHD - Japan Adult & Pediatric	1	7	2	2	2	2	7	9	11	12	13	14	16	17	18	19
Product & Royalty Revnues	**17**	**22**	**11**	**12**	**12**	**14**	**50**	**123**	**349**	**903**	**1,638**	**3,448**	**4,866**	**6,181**	**6,220**	**6,257**
Expenses																
MesoBlast COGS	-	-	3	3	3	4	13	23	68	134	227	343	485	616	620	624
COGS % Sales	0%	0%	30%	30%	30%	30%	30%	-20%	-20%	-15%	-14%	-10%	-10%	-10%	-10%	-10%
R&D	60	63	15	16	16	18	66	69	73	76	73	69	65	66	67	67
Manufacturing & Commercialization	15	16	7	8	8	9	32	26	21	20	19	18	18	17	16	16
Management & Adminastration	22	13	6	6	6	7	25	36	37	39	38	38	37	36	35	35
Total expenses	**97**	**92**	**31**	**33**	**34**	**38**	**136**	**153**	**198**	**269**	**357**	**468**	**605**	**736**	**739**	**741**
Oper. Inc. (Loss)	(80)	(70)	(20)	(21)	(22)	(24)	(87)	(31)	151	634	1,280	2,980	4,261	5,446	5,481	5,515
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)**	**(20)**	**(21)**	**(22)**	**(24)**	**(87)**	**(31)**	**151**	**634**	**1,280**	**2,980**	**4,261**	**5,446**	**5,481**	**5,515**
Pretax Margin																
Tax benefit (or expense)	9	2	-	-	-	-	-	-	(23)	(158)	(384)	(1,043)	(1,534)	(1,960)	(1,973)	(1,986)
Tax Rate		3%	0%	0%	0%	0%	0%	0%	15%	25%	30%	35%	36%	36%	36%	36%
Net Income	**(97)**	**(73)**	**(20)**	**(21)**	**(22)**	**(24)**	**(87)**	**(31)**	**128**	**475**	**896**	**1,937**	**2,727**	**3,485**	**3,508**	**3,530**
Net Margin																
EPS	**$ (0.72)**	**$ (0.63)**	**$ (0.15)**	**$ (0.16)**	**$ (0.14)**	**$ (0.16)**	**$ (0.62)**	**$ (0.20)**	**$ 0.85**	**$ 3.13**	**$ 5.88**	**$ 12.66**	**$ 17.76**	**$ 22.60**	**$ 22.66**	**$ 22.71**
Non GAAP EPS (dil)																
Wgtd Avg Shrs (Bas) - '000s	106	117	129	130	150	150	140	151	151	152	152	153	154	154	155	155
Wgtd Avg Shrs (Dil) - '000s	106	117	129	130	150	150	140	151	151	152	152	153	154	154	155	155

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.

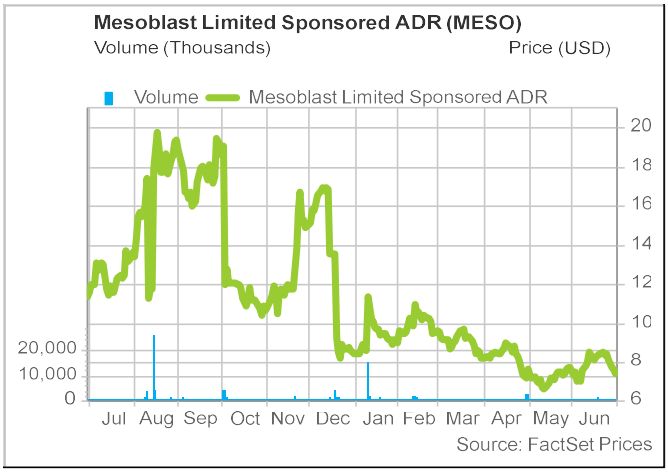
Legal and intellectual property risk. The company may have to defend its patents and technical know-how, and there can be no assurances that the patents will not be infringed or will be held as valid if challenged, and or that the company may infringe on third parties' patents.

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 related 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
Update – Buy – February 11, 2021 – Price Target $16.00
Update – Buy – March 8, 2021 – Price Target $16.00
Update – Buy – April 30, 2021 – Price Target $16.00
Update – Buy – June 3, 2021 – Price Target $16.00
Update – Buy – July 1, 2021 – Price Target $16.00

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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: 28-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%

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