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Mesoblast (NASDAQ/MESO, ASX/MSB)

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BUY: Novartis Partners with Mesoblast for ARDS – If It Works
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Mesoblast announced a deal with Novartis for remestemcel with an emphasis on ARDS, including COVID related disease. Mesoblast may receive a total of \$505M pending achievement of precommercialization milestones for ARDS indications. Post-commercialization milestones add up to \$750M plus tiered double-digit royalties on product sales.

Investment Highlights:

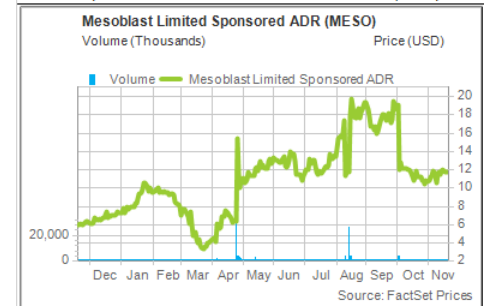
Remestemcel-L has potential for use in the treatment of ARDS. Published results from an investigator-initiated clinical study conducted in China reported that allogeneic MSCs cured or significantly improved functional outcomes in all seven treated patients with severe COVID-19 pneumonia. Mesoblast also reported that in a post-hoc analysis of a 60-patient randomized controlled study in chronic obstructive pulmonary disease (COPD), remestemcel-L infusions were well tolerated, significantly reduced inflammatory biomarkers, and significantly improved pulmonary function in those patients with elevated inflammatory biomarkers. Since the same inflammatory biomarkers are also elevated in COVID-19, these data suggest that remestemcel-L could be useful in the treatment of patients with ARDS due to COVID-19.

Trial Design. The trial is a randomized, double-blinded, controlled trial enrolling up to 300 ventilator-dependent patients with moderate to severe ARDS and aims to confirm findings from a pilot study at New York's Mt Sinai Hospital in March-April this year. In that study, nine of 12 ventilator-dependent patients (75%) were successfully discharged from hospital a median of 10 days after receiving two intravenous doses of remestemcel-L within five days.

Valuation. This is a complex discussion in terms of how does one value a company with both a commercially approved product, multiple partnerships, and 3 x 3 (three products in three pivotal trials, GvHD, Back Pain, and CHF). We model each product out to 2030. We provide a detailed explanation of our assumptions (pricing, timing) for each therapeutic model, and then "haircut" our estimates by a probability of success factor, based on the clinical stage of development and our assessment of the indication. For well-established companies with highly predictable revenues, we typically select a risk rate (r) of 10 percent; for early-stage growth companies like Mesoblast, we select our maximum risk rate of 30%. We assume dilution (we never let the projected balance sheet go negative) and use a fully diluted 2030 projected share count. These factors are then applied to our Free Cash Flow to the Firm (FCFF), Discounted EPS (dEPS), and Sum-of-the-Parts (SOP) models, which are equally weighted and rounded to the nearest whole number to derive a \$20.00 price target. Our model has previously assumed dilution, and as such, the recent raise does not impact our valuation.

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.

Current Price	\$11.79		
Price Target	\$20.00		
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)	-13.4	-18.9	-16.3
Stock Data			
52-Week Range	\$3.12	-	\$21.28
Shares Outstanding (mil.)	117.3		
Market Capitalization (mil.)	\$1,383		
Enterprise Value (mil.)	\$1,412		
Debt to Capital	6%		
Book Value/Share	\$6.02		
Price/Book	2.4		
Average Three Months Trading Volume (K)	997		
Insider Ownership	14.7%		
Institutional Ownership	28.4%		
Short interest (mil.)	2.8%		
Dividend / Yield	\$0.00/0.0%		


Please find Important Disclosures beginning on Page 5.

Valuation: Our valuation methodology begins with our projected revenues from our product models. 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 1. Free Cash Flow Model

Average	\$	20
Price Target	\$	20
Year		2020

DCF Valuation Using FCF (mln):													
Units (millions - \$)	2018A	2019A	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(66)	(105)	(75)	(87)	(31)	151	634	1,280	2,980	4,261	5,446	5,481	5,515
Tax Rate	0%	0%	3%	0%	0%	15%	25%	30%	35%	36%	36%	36%	36%
EBIT(1-t)	(66)	(105)	(73)	(87)	(31)	128	475	896	1,937	2,727	3,485	3,508	3,530
CapEx													
Depreciation													
Change in NWC													
FCF	(66)	(105)	(73)	(87)	(31)	128	475	896	1,937	2,727	3,485	3,508	3,530
PV of FCF	(111)	(137)	(73)	(87)	(18)	58	166	241	401	435	427	331	256
Discount Rate	30%												
Long Term Growth Rate	1%												
Free Cash Flow	12,294												
Terminal Value YE 2030	892												
NPV	3,050												
NPV/Debt	84												
Shares out (M)	146												
NPV Per Share	\$ 20												

Source: Dawson James estimates, company reports

Exhibit 2. Discounted-EPS Model

Year of EPS	2020
Year of EPS	2030
Earnings Multiple	10
Discount Factor	30%
Selected Year EPS	\$ 24.20
NPV	\$ 18

Discount Rate and Earnings Multiple Varies, Year is Constant							
2030 EPS							
	10%	15%	20%	25%	30%	35%	
Earnings Multiple	1	\$7.49	\$4.80	\$3.14	\$2.09	\$1.41	\$ 0.97
	5	\$37.46	\$24.02	\$15.69	\$10.43	\$7.05	\$ 4.83
	10	\$74.92	\$48.03	\$31.38	\$20.87	\$14.10	\$ 9.66
	15	\$112.38	\$72.05	\$47.08	\$31.30	\$21.14	\$ 14.50
	20	\$149.84	\$96.07	\$62.77	\$41.73	\$28.19	\$ 19.33
	25	\$187.30	\$120.08	\$78.46	\$52.16	\$35.24	\$ 24.16
	30	\$224.76	\$144.10	\$94.15	\$62.60	\$42.29	\$ 28.99
	35	\$262.22	\$168.12	\$109.84	\$73.03	\$49.33	\$ 33.83

Source: Dawson James estimates

Exhibit 3. Sum-of-the-Parts Model

Mesoblast Sum of the Parts	LT Gr	Discount Rate	Yrs. to Mkt	% Success	Peak Sales MMs	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%	1	100%	\$319	\$1,101
NPV						\$2.90
Acute Pediatric GvHD - E.U.	1%	30%	1	100%	\$108	\$372
NPV						\$0.98
Acute Adult GvHD E.U.	1%	30%	1	100%	\$383	\$1,322
NPV						\$3.48
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						\$21

Source: Dawson James estimates

Exhibit 4. 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																
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	-	-	-	-	-	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	-	-	-	-	-	-	-	-	-	-
Total other income	(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.

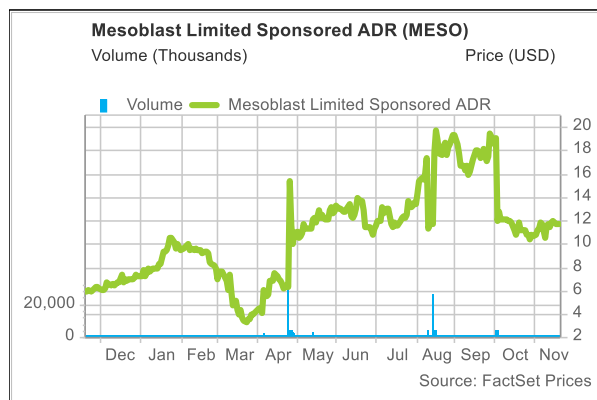
Partnership risk. Mesoblast may seek partnerships for clinical development support and commercialization. We have no specific knowledge of any discussions with possible partners today, and there can be no assurances that the company will be able to secure a favorable partnership.

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
- 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

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- 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.

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Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	21	78%	4	19%
Market Perform (Neutral)	6	22%	1	17%
Market Underperform (Sell)	0	0%	0	0%
Total	27	100%	5	19%

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