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Mesoblast (NASDAQ/MESO, ASX/MSB)
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BUY: COVID-19 ARDS Virus – ½ Way Enrolled
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Mesoblast announced today that the randomized controlled Phase 3 trial of remestemcel-L on top of maximal care in ventilator-dependent patients with acute respiratory distress syndrome (ARDS) due to COVID-19 infection has surpassed 50% enrollment. The trial's primary endpoint is reduction in 30-day mortality relative to maximal care. ARDS continues to be the primary cause of death in COVID-19 patients.

Investment Highlights:

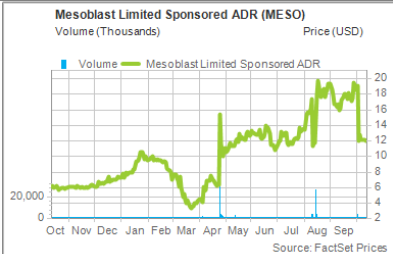
Remestemcel-L has potential for use in the treatment of ARDS. Published results from an investigator-initiated clinical study conducted in China reported that allogeneic MSCs cured or significantly improved functional outcomes in all seven treated patients with severe COVID-19 pneumonia. Mesoblast also 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	\$12.01		
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)	-13.6	-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%		



Mesoblast Limited Sponsored ADR (MESO)
 Volume (Thousands) Price (USD)

Source: FactSet Prices

How is the Remestemcel-L COVID-19 ARDS Program Progressing? *During the period March-April 2020, 12 ventilator-dependent COVID-19 patients with moderate/severe COVID-19 ARDS were treated with two infusions of remestemcel-L within the first five days under emergency compassionate use at New York City's Mt Sinai hospital. Nine patients successfully came off ventilator support at a median of 10 days and were discharged from hospital.*

These results contrast with only 9% of ventilator-dependent COVID-19 patients being able to come off ventilators with standard of care treatment at two major referral hospital networks in New York during the same time period. This compassionate use treatment experience has informed the design of the clinical protocol for the randomized, placebo-controlled Phase 3 trial of remestemcel-L in ventilator-dependent COVID-19 moderate/severe ARDS patients in Northern America.

First patients have been dosed in the Phase 3 randomized placebo-controlled trial in the United States of remestemcel-L in COVID-19 infected patients with moderate to severe ARDS on ventilator support. Enrollment is underway in up to 30 leading medical centers across North America and is expected to complete within three to four months, with interim analyses planned, which could result in stopping the trial early for efficacy or futility.

The trial is randomized up to 300 ventilator-dependent patients in intensive care units to either remestemcel-L or placebo (1:1) on top of maximal care, in line with specific guidance provided by the FDA for robust statistical analysis. The primary endpoint is all-cause mortality within 30 days of randomization, with the key secondary endpoint being the number of days alive and off mechanical support.

Exhibit 1. Phase 3 Trial in COVID-ARDS Patients

Objective:

- Multi-center, randomized, controlled, blinded study to assess safety and efficacy of remestemcel-L versus standard of care (SOC) treatment in subjects with moderate/severe ARDS on ventilator due to COVID-19
- The trial will be conducted at up to 30 major teaching hospitals across North America

Trial design:

- 300 patients 1:1 randomized (150 SOC + remestemcel-L : 150 SOC + placebo)
- Dose is two infusions of remestemcel-L (2×10^6 cells/kg/dose) in the first week

Primary endpoint: all cause mortality up to 30 days post randomization

Key secondary endpoint: days alive off ventilator within 60 days

Additional information:

- Recruitment is expected to complete within three to four months, with interim analyses planned which could result in stopping the trial early for efficacy or futility

Source: Mesoblast

Exhibit 2. Pilot Data Supports the Rationale for COVID Pivotal trial**Compassionate Use Data from Emergency IND**

- 12 patients with moderate or severe ARDS received two infusions of remestemcel-L at Mt. Sinai Hospital in New York City
- Nine patients successfully came off ventilator support at a median of 10 days and were discharged from hospital
- This contrasts with only 9% of COVID-19 patients able to be extubated and a 12% survival rate in two major NY hospital networks during same time period^{1,2}

Confirmatory Phase 3 Trial

- Up to 300 patients randomized 1:1 to remestemcel-L or placebo
- Primary endpoint Day 30 mortality; Key secondary endpoint days alive off ventilator support
- First patients randomized and dosed in early May

Source: Mesoblast

Exhibit 3. COVID Trial Milestones

- Recruitment is expected to take three to four months
- Interim analyses planned which could result in stopping the trial early for efficacy or futility. First interim analysis when 30% of patients reach the primary endpoint
- Seek expedited regulatory approval subject to positive data read-out
- Manufacturing scale-up to meet projected increase in capacity requirements for maturing pipeline, including GVHD label extensions and COVID-19 ARDS
 - Increase manufacturing footprint for capacity expansion
 - Implement proprietary xeno-free technologies to increase yields and output
 - Plan for long-term move to 3D bioreactors to reduce labor and improve manufacturing efficiencies
- Establish manufacturing and commercialization partnerships

Source: Mesoblast

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 4. 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													
Long Term Growth Rate													
Free Cash Flow		12,284											
Terminal Value YE 2030		892											
NPV		3,050											
NPV-Debt		84											
Shares out (M)		146	2030E										
NPV Per Share	\$	20											

Source: Dawson James estimates, company reports

Exhibit 5. Discounted-EPS Model

Year of EPS	2020
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 6. 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 7. 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																
Discogetic 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 Revnues	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																
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)																
Wgtd Avg Shrs (Bas) - '000s	106	108	120	120	120	117	141	141	142	142	143	144	144	145	145	146
Wgtd 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 party's patents.

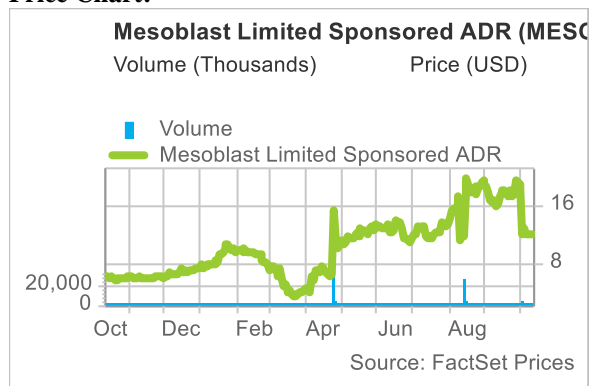
Partnership risk. Mesoblast may seek partnerships for clinical development support and commercialization. We have no specific knowledge of any discussions with possible partners today, and there can be no assurances that the company will be able to secure a favorable partnership.

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

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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)	23	85%	4	17%
Market Perform (Neutral)	4	15%	1	25%
Market Underperform (Sell)	0	0%	0	0%
Total	27	100%	5	19%

Analyst Certification:

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