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Mesoblast (NASDAQ/MESO, ASX/MSB)

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BUY: Closing in on GvHD, COVID, DDD and CHF

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Mesoblast did meet with the FDA to define the pathway to US regulatory approval for rexlemestrocel-L for pediatric steroid refractory GvHD and for adult COVID patients suffering from ARDS. We are also focused on clinical progress in the degenerative disc disease and CHF programs.

Investment Highlights:

Remestemcel-L

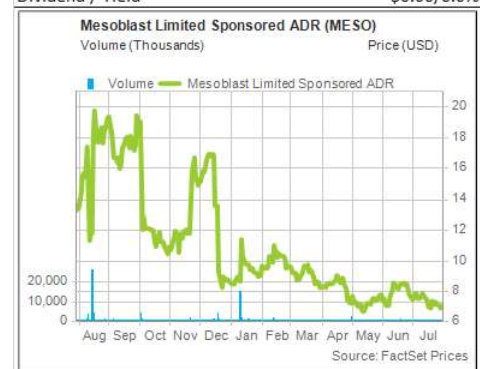
- **Steroid Refractory (SR) aGvHD: What's Next?** Regarding SR-aGvHD, FDA's Center for Biologics Evaluation and Research (CBER) recommended that Mesoblast, as a next step, discuss with CBER's review team at the Office of Tissue and Advanced Therapies (OTAT) the approach to address certain outstanding chemistry, manufacturing and controls (CMC) items, including potency assays, which could support a resubmission of the current Biologic License Application (BLA) with a six-month review period.
- **COVID Data:** The current data (randomized trial in n=222 patients, ventilator dependent) set showed improved respiratory function in patients treated with remestemcel-L, as well as 90-day survival outcomes showing remestemcel-L significantly reduced mortality by 48% at 90 days compared to controls in a pre-specified analysis of 123 treated patients under 65 years old.
- **Remember...Novartis is partnered with Mesoblast.** The license and collaboration agreement is for the development, manufacture, and commercialization of remestemcel-L, with an initial focus on the development of the treatment of ARDS, and remains subject to certain closing conditions, including time during this period to analyze the results from the COVID-19 ARDS trial.

Rexlemestrocel-L

- **Back Pain.** Mesoblast intends to meet with FDA to discuss a potential pathway for approval of rexlemestrocel-L in patients with chronic discogenic lower back pain based on the observed durable reduction in pain and opioid sparing activity in the CLBP Phase 3 trial. Mesoblast and its partner in Europe and Latin America, Grünenthal, amended their collaboration agreement in line with a strategy to achieve regulatory harmonization, cost efficiencies and streamlined timelines aiming to leverage the results from a planned US trial in support of potential product approvals in both the US and EU.
- **Balance Sheet:** Mesoblast announced results for the current cash on hand (end of the quarter) of \$136M. Multiple partners including Novartis are now working with the company to achieve a transition (pending approval) to commercialization.

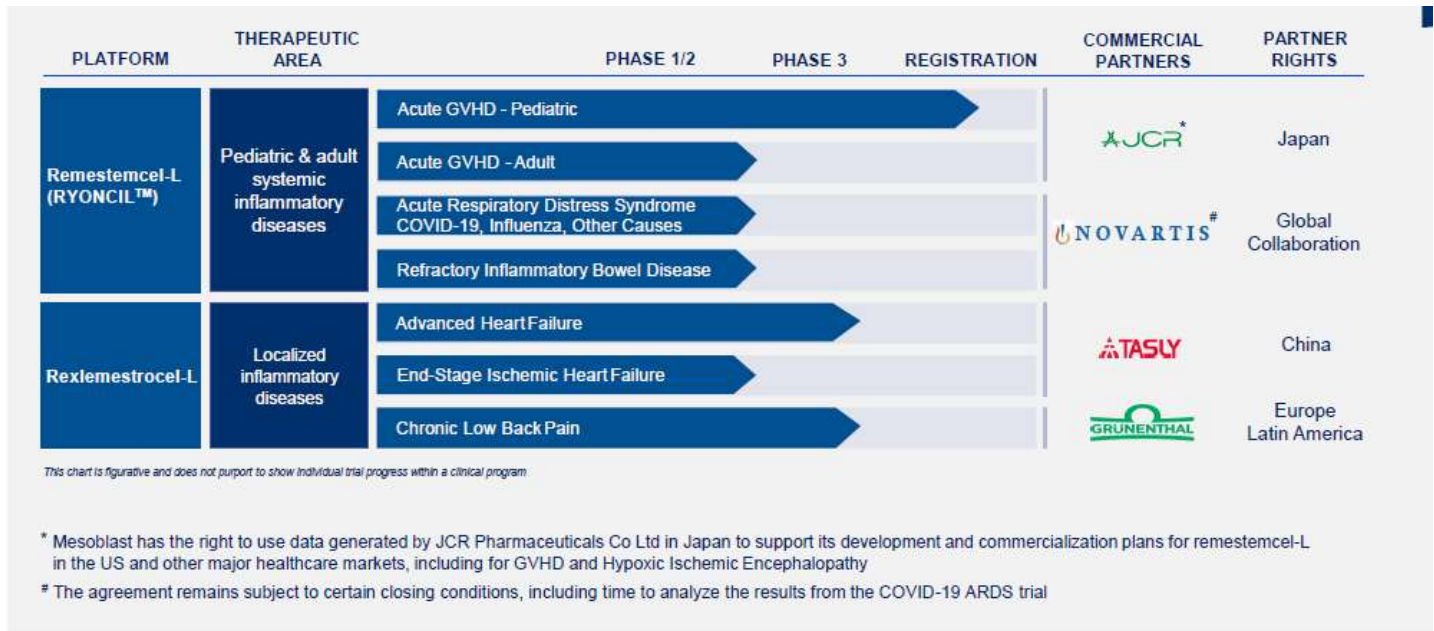
Valuation: Our valuation methodology begins with our projected revenues from our product models, which are adjusted by a probability of success or risk factor. We apply assumptions for the timing of approval, launch dates, and product attributes to estimate revenues. These estimates feed into our income 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.

Current Price	\$7.06
Price Target	\$16.00
Mesoblast's portfolio of Phase 3 product candidates are:	
<ul style="list-style-type: none"> • 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	\$6.67 - \$21.28
Shares Outstanding (mil.)	129.7
Market Capitalization (mil.)	\$916
Enterprise Value (mil.)	\$945
Book Value/Share	\$6.02
Price/Book	2.4
Average Three Months Trading Volume (K)	483
Insider Ownership	13.2%
Institutional Ownership	25.2%
Short interest (mil.)	1.1%
Dividend / Yield	\$0.00/0.0%



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

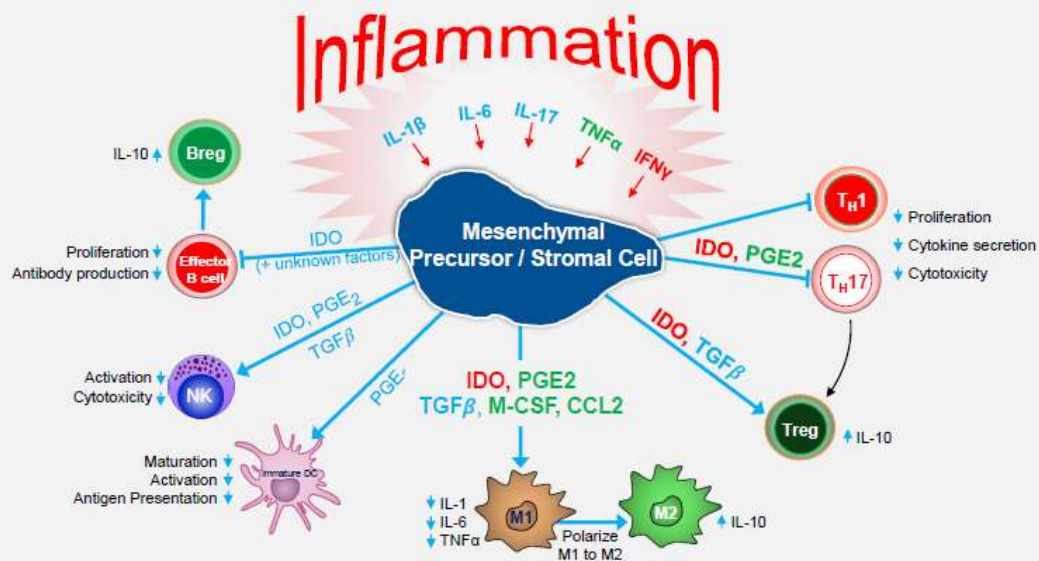
Exhibit 1. Pipeline



Source: Mesoblast

Exhibit 2. This is a Platform Technology

Our mesenchymal precursor/stromal cells respond to and are activated by multiple inflammatory cytokines through surface receptors, resulting in orchestration of an anti-inflammatory cascade



Source: Mesoblast

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 Revenues	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 & Administration	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.

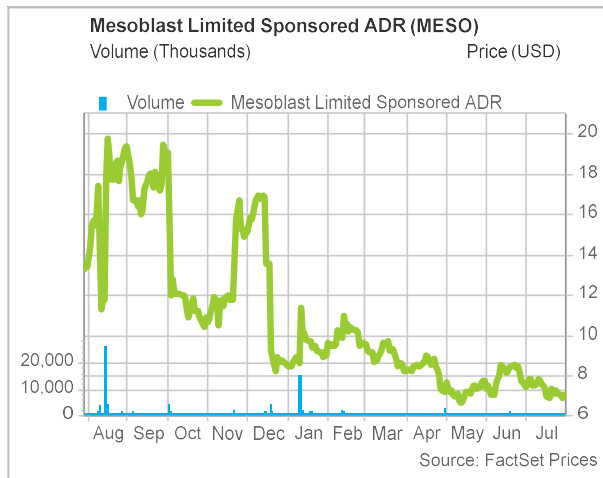
Partnership risk. Mesoblast may seek partnerships for clinical development support and commercialization. We have no specific knowledge of any discussions with possible partners today, and there can be no assurances that the company will be able to secure a favorable partnership.

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
 Update – Buy – July 30, 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-Jul-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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