

## Mesoblast (NASDAQ/MESO, ASX/MSB)

October 2, 2020

### BUY: Remestemcel–CRL, but We Could Still see an Approval

**Jason Kolbert**

**Healthcare Research**

**jkolbert@dawsonjames.com**

The FDA has issued a Complete Response Letter (CRL) to Mesoblast for its 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.

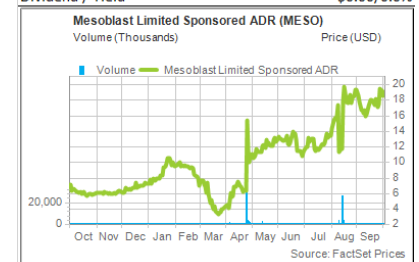
### Investment Highlights:

**So, What Happened?** We believe a combination of the Osiris – Prochymal legacy of manufacturing, mechanism of action, and a broad mix of data came into focus for regulators that raised some questions. The totality of the data suggests the product works and is safe. We believe manufacturing issues have now been worked out, and Mesoblast is addressing the concerns regarding these and other issues. In the interim period, the same product is in a pivotal COVID-ARDS trial. Good data from that trial should support approval in GvHD with a post-marketing plan to meet regulators' requirements for an “additional confirming trial.”

### Remestemcel-L for Pediatric GvHD: The Data. Three studies.

- Study 275:** An Expanded Access Program in 241 children across 50 centers in eight countries where RYONCIL was used as salvage therapy for steroid-refractory acute GVHD in patients who failed to respond to steroid therapy as well as multiple other agents. Day 28 Overall Response (OR), the primary endpoint, was achieved in 65% of subjects. Survival through 100 days was significantly greater in patients who achieved a day 28 OR (82%) compared with patients that did not achieve day 28 OR (39%), with 67% overall day 100 survival.
- Study GVHD001/002:** A Phase 3 single-arm trial in 55 children across 20 centers in the United States where RYONCIL was used as the first line of treatment for children who failed to respond to steroids for acute GVHD. Consistent with the findings in Study 275, Day 28 OR was achieved in 70% of children. This was statistically significant compared to the pre-specified control value of 45% (70.4% versus 45%, P =0.0003). As in study 275, clinical response at day 28 was highly predictive of improved survival through day 100 (87% compared to 47% in patients that did not achieve day 28 OR P = 0.0001). Similar predictive value of day 28 was also seen in survival through day 180 (79% vs. 43.8%, P= 0.003). Overall survival was 74.1% at day 100 and 68.5% at day 180. These results were significantly higher than those from matched control pediatric subjects from the contemporaneous database of the Mount Sinai Acute GVHD International Consortium (MAGIC), accessed to provide an unbiased and independent estimate of response rates and outcomes in matched pediatric control patients treated with institutional standard of care. In the MAGIC controls, Day 28 OR was 43%, and Day 100 survival was 57%

Current Price	\$11.94		
Price Target	\$20.00		
<b>Estimates</b>	<b>F2019A</b>	<b>F2020E</b>	<b>F2021E</b>
<b>Expenses (\$000s)</b>	\$ 97	\$ 92	\$ 136
1Q March	\$ 28	\$ 28	\$ 31
2Q June	\$ 27	\$ 22	\$ 33
3Q September	\$ 23	\$ 23	\$ 34
4Q December	\$ 19	\$ 19	\$ 38
<b>EPS (diluted)</b>	<b>F2019A</b>	<b>F2020E</b>	<b>F2021E</b>
	\$ (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)
<b>EBITDA/Share</b>	<b>(\$0.90)</b>	<b>(\$0.53)</b>	<b>(\$0.61)</b>
<b>EV/EBITDA (x)</b>	<b>-13.6</b>	<b>-19.1</b>	<b>-16.5</b>
<b>Stock Data</b>			
52-Week Range	\$3.12	-	\$21.28
Shares Outstanding (mil.)	117.3		
Market Capitalization (mil.)	\$1,401		
Enterprise Value (mil.)	\$1,430		
Debt to Capital	6%		
Book Value/Share	\$6.02		
Price/Book	2.4		
Average Three Months Trading Volume (K)	273		
Insider Ownership	21.1%		
Institutional Ownership	26.9%		
Short Interest (mil.)	2.3%		
Dividend / Yield	\$0.00/0.0%		



3. **Study 280:** A Phase 3 randomized placebo-controlled trial in 260 patients, including 28 children, across 72 centers in seven countries where RYONCIL or placebo were added to second line therapy in patients with steroid-refractory acute GVHD who failed to respond to steroid treatment. Among high-risk children and adults who had the most severe disease stages, day 28 OR was significantly greater in the RYONCIL treated group (58% versus 37%;  $P = 0.03$ ) compared to placebo. Among the standard risk patients there was no significant benefit of RYONCIL treatment. Within the pediatric patients in this study ( $n=28$ ) day 28 OR was significantly greater in the RYONCIL group compared with the placebo group (64% vs 36%, respectively,  $P=0.05$ ). These Phase 3 results provide prospective, randomized controlled data which are supportive for the use of RYONCIL in children and high-risk adults with steroid-refractory acute GVHD.

**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.

**How Does Clinical Success Change the Projected Valuation?** For example, we assume just a 40% success probability in the CHF indications (even though the trial is pivotal). If Mesoblast announces positive clinical data, it suggests the probability goes up. At 100%, this change alone would drive a substantially higher valuation target.

**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.

**Modeling Assumptions for GVHD (Remestemcel-L)**

1. We assume a 2% annual market size growth for all patients with GvHD.
2. We assume the cost of therapy for GvHD is \$250,000 in the U.S. and will decrease to \$212,200 by 2030.
3. We assume the cost of therapy for GvHD is \$230,000 in the E.U. and will decrease to \$195,224 by 2030.
4. We assume the cost of therapy for GvHD in Japan will decrease to \$125,000 by 2030.
5. We assume market share penetration for pediatric GvHD in the U.S. will be 3% in 2019 and increase to 85% by 2030.
6. We assume market share penetration for adult GvHD in the U.S. will be 25% beginning in 2022 and will increase to 85% by 2030.
7. We assume market share penetration for pediatric GvHD in the E.U. will be 3% in 2019 and increase to 85% by 2030.
8. We assume market share penetration for adult GvHD in the E.U. will be 25% beginning in 2022 and increase to 85% by 2030.
9. We assume market share penetration for GvHD in Japan to be 30% by 2030.
10. We assume the probability of success for all GvHD patients is 70%.

**Exhibit 1. GvHD Model(s)**

	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
<b>Pediatric GvHD - USA</b>											
Allogeneic Stem Cell Transplants	16000	16320	16647	16980	17319	17666	18019	18379	18747	19122	19504
Market Size Growth (Annual)	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%
Ped. & Adult Acute GvHD (grades II-IV)	8679	8853	9030	9210	9394	9582	9774	9969	10169	10372	10580
Pediatric Steroid Refractory Acute GvHD (Grades II-IV)	672	686	699	713	728	742	757	772	787	803	819
Market Share Penetration	0.0%	25.0%	50.0%	75.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%
Number of Patients Procedures	0	171	350	535	618	631	643	656	669	683	696
Cost of Therapy	\$ 250,000	\$ 250,000	\$ 250,000	\$ 247,500	\$ 235,125	\$ 223,369	\$ 212,200	\$ 212,200	\$ 212,200	\$ 212,200	\$ 212,200
Price Change	0%	0%	0%	-1%	-5%	-5%	-5%	0%	0%	0%	0%
Probability of Success	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%
Pediatric Acute GvHD Grades II-IV Revenues (M)	\$ -	\$ 30	\$ 61	\$ 93	\$ 102	\$ 99	\$ 96	\$ 97	\$ 99	\$ 101	\$ 103
<b>Adult GvHD - USA</b>											
Allogeneic Stem Cell Transplants	16000	16320	16647	16980	17319	17666	18019	18379	18747	19122	19504
Market Size Growth (Annual)	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%
Ped. & Adult Acute GvHD (grades II-IV)	8679	8853	9030	9210	9394	9582	9774	9969	10169	10372	10580
Adult Steroid Refractory (liver involvement / high risk, Grades II-IV)	1605	1637	1670	1704	1738	1772	1808	1844	1881	1919	1957
Market Share Penetration	0.0%	0.0%	25.0%	50.0%	75.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%
Number of Patients Procedures	0	0	418	852	1,303	1,507	1,537	1,567	1,599	1,631	1,663
Cost of Therapy	\$ 250,000	\$ 250,000	\$ 250,000	\$ 247,500	\$ 235,125	\$ 223,369	\$ 212,200	\$ 212,200	\$ 212,200	\$ 212,200	\$ 212,200
Price Change	0%	0%	0%	-1%	-5%	-5%	-5%	0%	0%	0%	0%
Probability of Success	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%
Adult Acute GvHD Revenues (M)	\$ -	\$ -	\$ 73	\$ 148	\$ 214	\$ 236	\$ 228	\$ 233	\$ 237	\$ 242	\$ 247
<b>Pediatric GvHD - EU</b>											
Allogeneic Stem Cell Transplants	20233	20637	21050	21471	21900	22338	22785	23241	23706	24180	24663
Market Size Growth (Annual)	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%
Ped. & Adult Acute GvHD (grades II-IV)	10723	10938	11157	11380	11607	11840	12076	12318	12564	12815	13072
Pediatric Steroid Refractory Acute GvHD (Grades II-IV)	555	566	577	588	600	612	624	637	650	663	676
Market Share Penetration	0.0%	25.0%	50.0%	75.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%
Number of Patients Procedures	0	141	288	441	510	520	531	541	552	563	575
Cost of Therapy	\$ 230,000	\$ 230,000	\$ 230,000	\$ 227,700	\$ 216,315	\$ 205,499	\$ 195,224	\$ 195,224	\$ 195,224	\$ 195,224	\$ 195,224
Price Change	0%	0%	0%	-1%	-5%	-5%	-5%	0%	0%	0%	0%
Probability of Success	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%
Pediatric Acute GvHD Grades II-IV Revenues (M)	\$ -	\$ 23	\$ 46	\$ 70	\$ 77	\$ 75	\$ 73	\$ 74	\$ 75	\$ 77	\$ 79
<b>Adult GvHD - EU</b>											
Allogeneic Stem Cell Transplants	20233	20637	21050	21471	21900	22338	22785	23241	23706	24180	24663
Market Size Growth (Annual)	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%
Ped. & Adult Acute GvHD (grades II-IV)	10723	10938	11157	11380	11607	11840	12076	12318	12564	12815	13072
Adult Steroid Refractory (liver involvement / high risk, Grades II-IV)	2094	2136	2179	2223	2267	2312	2359	2406	2454	2503	2553
Market Share Penetration	0.0%	0.0%	25.0%	50.0%	75.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%
Number of Patients Procedures	0	0	545	1,111	1,700	1,965	2,005	2,045	2,086	2,127	2,170
Cost of Therapy	\$ 230,000	\$ 230,000	\$ 230,000	\$ 227,700	\$ 216,315	\$ 205,499	\$ 195,224	\$ 195,224	\$ 195,224	\$ 195,224	\$ 195,224
Price Change	0%	0%	0%	-1%	-5%	-5%	-5%	0%	0%	0%	0%
Probability of Success	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%
Adult Acute GvHD Revenues (M)	\$ -	\$ -	\$ 88	\$ 177	\$ 257	\$ 283	\$ 274	\$ 279	\$ 285	\$ 291	\$ 297
<b>GvHD - Japan</b>											
Allogeneic Stem Cell Transplants	4085	4167	4250	4335	4422	4510	4600	4692	4786	4882	4980
Market Size Growth (Annual)	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%
Ped. & Adult Acute GvHD (grades II-IV)	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%
Number of Patients Procedures	1,430	1,458	1,488	1,517	1,548	1,579	1,610	1,642	1,675	1,709	1,743
Market Share Penetration	14.0%	16.0%	20.0%	24.0%	30.0%	34.0%	36.0%	38.0%	40.0%	42.0%	44.0%
Number of Patients Procedures	200	233	298	364	464	537	580	624	670	718	767
Cost of Therapy	\$ 170,000	\$ 150,000	\$ 150,000	\$ 150,000	\$ 125,000	\$ 125,000	\$ 125,000	\$ 125,000	\$ 125,000	\$ 125,000	\$ 125,000
Revenues	\$ 34	\$ 35	\$ 45	\$ 55	\$ 58	\$ 67	\$ 72	\$ 78	\$ 84	\$ 90	\$ 96
Japan Annual Royalty/Revenues to Mesoblast: 20%	\$ 6.8	\$ 7.0	\$ 8.9	\$ 10.9	\$ 11.6	\$ 13.4	\$ 14.5	\$ 15.6	\$ 16.8	\$ 17.9	\$ 19.2
% Growth (qtrly)	376%	3%	28%	22%	6%	16%	8%	8%	7%	7%	7%

Source: Dawson James Estimates

**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 2. 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 ( $2 \times 10^6$  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 3. Pilot Data Supports the Rational 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<sup>1,2</sup>

**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 4. 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 5. 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 6. 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 7. 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 8. 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																
Disogenic 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																
<b>Product Revenues</b>	<b>15</b>	<b>12</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>12</b>	<b>43</b>	<b>114</b>	<b>338</b>	<b>891</b>	<b>1,624</b>	<b>3,434</b>	<b>4,850</b>	<b>6,164</b>	<b>6,202</b>	<b>6,238</b>
TemCell GvHD - Japan Adult & Pediatric	1	2	2	2	2	7	7	9	11	12	13	14	16	17	18	19
<b>Product &amp; Royalty Revenues</b>	<b>17</b>	<b>17</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>22</b>	<b>50</b>	<b>123</b>	<b>349</b>	<b>903</b>	<b>1,638</b>	<b>3,448</b>	<b>4,866</b>	<b>6,181</b>	<b>6,220</b>	<b>6,257</b>
<b>Expenses</b>																
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
<b>Total expenses</b>	<b>97</b>	<b>28</b>	<b>22</b>	<b>23</b>	<b>19</b>	<b>92</b>	<b>136</b>	<b>153</b>	<b>198</b>	<b>269</b>	<b>357</b>	<b>468</b>	<b>605</b>	<b>736</b>	<b>739</b>	<b>741</b>
<b>Oper. Inc. (Loss)</b>	<b>(80)</b>	<b>(11)</b>	<b>(20)</b>	<b>(21)</b>	<b>(17)</b>	<b>(70)</b>	<b>(87)</b>	<b>(31)</b>	<b>151</b>	<b>634</b>	<b>1,280</b>	<b>2,980</b>	<b>4,261</b>	<b>5,446</b>	<b>5,481</b>	<b>5,515</b>
<b>Oper Margin</b>																
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	-	-	-	-	-	-	-	-	-	-
<b>Pre-tax income</b>	<b>(105)</b>	<b>(16)</b>	<b>(20)</b>	<b>(21)</b>	<b>(17)</b>	<b>(75)</b>	<b>(87)</b>	<b>(31)</b>	<b>151</b>	<b>634</b>	<b>1,280</b>	<b>2,980</b>	<b>4,261</b>	<b>5,446</b>	<b>5,481</b>	<b>5,515</b>
<b>Pretax Margin</b>																
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%
<b>Net income</b>	<b>(97)</b>	<b>(15)</b>	<b>(20)</b>	<b>(21)</b>	<b>(17)</b>	<b>(73)</b>	<b>(87)</b>	<b>(31)</b>	<b>128</b>	<b>475</b>	<b>896</b>	<b>1,937</b>	<b>2,727</b>	<b>3,485</b>	<b>3,508</b>	<b>3,530</b>
<b>Net Margin</b>																
<b>EPS</b>	<b>\$ (0.72)</b>	<b>\$ (0.14)</b>	<b>\$ (0.17)</b>	<b>\$ (0.18)</b>	<b>\$ (0.14)</b>	<b>\$ (0.63)</b>	<b>\$ (0.62)</b>	<b>\$ (0.22)</b>	<b>\$ 0.90</b>	<b>\$ 3.34</b>	<b>\$ 6.27</b>	<b>\$ 13.49</b>	<b>\$ 18.92</b>	<b>\$ 24.08</b>	<b>\$ 24.14</b>	<b>\$ 24.20</b>
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.

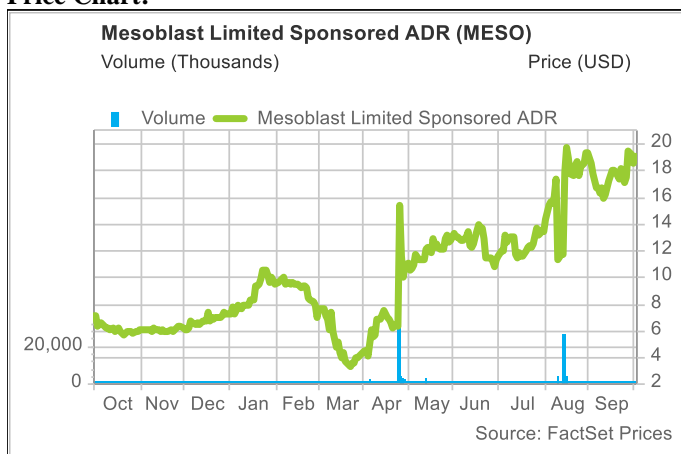


**Important Disclosures:**

**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

Dawson James Securities, Inc. (the "Firm") is a member of the Financial Industry Regulatory Authority ("FINRA") and the Securities Investor Protection Corporation ("SIPC").

The Firm does not make a market in the securities of the subject company(s). The Firm has NOT engaged in investment banking relationships with MESO in the prior twelve months, as a manager or co-manager of a public offering and has NOT received compensation resulting from those relationships. The Firm may seek compensation for investment banking services in the future from the subject company(s). The Firm has NOT received other compensation from the subject company(s) in the last 12 months for services unrelated to managing or co-managing of a public offering.

Neither the research analyst(s) whose name appears on this report nor any member of his (their) household is an officer, director or advisory board member of these companies. The Firm and/or its directors and employees may own securities of the company(s) in this report and may increase or decrease holdings in the future. As of September 31, 2020, the Firm as a whole did not beneficially own 1% or more of any class of common equity securities of the subject company(s) of this report. The Firm, its officers, directors, analysts or employees may affect transactions in and have long or short positions in the securities (or options or warrants related to those securities) of the company(s) subject to this report. The Firm may affect transactions as principal or agent in those securities.

Analysts receive no direct compensation in connection with the Firm's investment banking business. All Firm employees, including the analyst(s) responsible for preparing this report, may be eligible to receive non-product or service specific monetary bonus compensation that is based upon various factors, including total revenues of the Firm 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.

Although the statements in this report have been obtained from and are based upon recognized statistical services, issuer reports or communications, or other sources that the Firm believes to be reliable, we cannot guarantee their accuracy. All opinions and estimates included in this report constitute the analyst's judgment as of the date of this report and are subject to change without notice.

**Information about valuation methods and risks can be found in the "VALUATION" and "RISK ANALYSIS" sections of this report.**

The securities of the company discussed in this report may be unsuitable for investors depending on their specific investment objectives and financial position. This report is offered for informational purposes only and does not constitute an offer or solicitation to buy or sell any securities discussed herein in any jurisdiction where such would be prohibited. Additional information is available upon request.

**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:**

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.