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Mesoblast (NASDAQ/MESO, ASX/MSB)

August 24, 2020

BUY: Raising Price Target to $20.00 (from $15.00) as Remestemcel Receives Positive ODAC Vote in SR-aGVHD

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The FDA's Oncologic Drugs Advisory Committee (ODAC)voted overwhelmingly in favor that the available data support the efficacy of remestemcel-L (RYONCIL) in pediatric patients with steroid-refractory acute graft versus host disease (SR-aGVHD). We have adjusted our probability of success in our model, which drives our price target from $15.00 to $20.00. In addition, we are watching the Phase 3 trial of remestemcel-L in COVID-19 patients with acute respiratory distress syndrome.

Investment Highlights:

Remestemcel-L for SR-aGVHD and Other Inflammatory Diseases

- FDA has set a Prescription Drug User Fee Act (PDUFA) action date for RYONCIL in the treatment of pediatric SR-aGVHD of September 30, 2020
- If approved, US launch of RYONCIL planned for Q420
- Execute lifecycle extension strategy with investigator-initiated and sponsored clinical trials for Pediatric and Adult systemic inflammatory diseases.

COVID-19: Remestemcel-L for Acute Respiratory Distress Syndrome (ARDS)

- Complete recruitment of Phase 3 trial
- 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
- Expansion into additional causes of ARDS including influenza and bacterial infection
- Establish strategic partnerships for manufacturing and commercialization.

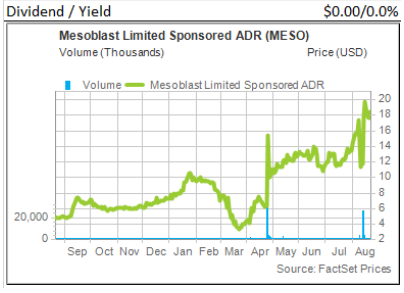
REVASCOR for Advanced and End-Stage Heart Failure

- In the Phase 3 randomized controlled trial of Revascor for advanced heart failure, final study visits for all surviving patients have been completed, ongoing quality review of all data is being completed at the study sites, with a data readout planned later this year.
- Initiate confirmatory trial in ischemic end-stage heart failure patients.

MPC-06-ID for Chronic Low Back Pain

- In the Phase 3 randomized controlled trial of MPC-06-ID for chronic low back pain due to degenerative disc disease, final study visits for all patients have been completed, ongoing quality review of all data is being completed at the study sites, with a data readout planned for mid-2020
- Work together with Grünenthal to complete clinical protocol design, obtain regulatory input, and receive clearance from European regulatory authorities to begin European Phase 3 trial

Current Price			**$18.51**
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)	-20.8	-29.3	-25.3
Stock Data			
52-Week Range	$3.12	-	$21.28
Shares Outstanding (mil.)			117.0
Market Capitalization (mil.)			$2,165
Enterprise Value (mil.)			$2,194
Debt to Capital			4%
Book Value/Share			$6.02
Price/Book			1.1
Average Three Months Trading Volume (K)			412
Insider Ownership			21.2%
Institutional Ownership			27.4%
Short interest (mil.)			1.4%
Dividend / Yield			$0.00/0.0%



Heart Failure (HF) is a Blockbuster Opportunity. Advanced stage and end-stage heart failure impact more than eight million people in the U.S. alone. Treatment options today tend to work on easing symptoms with just a modest effect on the therapeutic course of the disease. Advanced stage heart failure has the highest event rate, costing the U.S. healthcare system $115B per year and accounts for more than two-thirds of all hospital expenditures. Mesoblast is close to completing its Phase 3 trial of Revascor in HF. This is an event-driven trial, and the trial has now surpassed the number of events required (for trial completion).

A New Treatment Paradigm in Back Pain – Moving Beyond Steroids and Opiates. From the time man crawled out of the primordial ooze and stood upright as a biped, back-pain followed. Chronic lower back pain (CLBP) likely results in more disabilities than just about any other condition. With the recognition of the hazards of prescribing opiates to treat pain (the symptom), versus addressing the underlying cause, such as a herniated disc and in its final stages spinal fusion (surgery), a new modality is needed. Mesoblast's CLBP could be the solution, literally swapping cells for steroids for injection into the intra-vertebral space, supporting repair of the underlying cause, disc herniation, and the resulting inflammation.

The Achilles Heel of Cell Therapy - Manufacturing, Manufacturing, and Manufacturing. Mesoblast has been working with Lonza (LZAGY-Not rated) on developing and perfecting the process for manufacturing. Tightly controlling the doublings and number of passages, without compromising cell integrity. Given the size of the markets (CHF, DDD), the ability to have an off-the-shelf ready product is likely to be a key area of concern for the regulators. We have carefully noted over the years, the effort behind the process, and the time and resources that Mesoblast has allocated with Lonza to achieve production goals. What's important to understand is that as an allogenic product, the process, while arduous, is not comparable to the obstacles presented in gene Therapy and or the CAR-T space.

3 X 3 - Commercialization is Right Around the Corner. With three products in Phase 3 trials, commercialization is likely coming soon. Add it up, the low risk of adverse events, the ability to manufacture millions of doses, and the unmet medical needs in blockbuster market opportunities such as H.F. and DDD. We could see an industry shift as regenerative medicine is recognized.

Efficiently Raising the Capital to Get There – Multiple Levers to Pull. Mesoblast has already accomplished what no other regenerative medicine company has done, in terms of capital raising through a range of methods from a who's who list of partnerships, creative loans, and smart raises down under (Australia) with an eye towards managing shareholder value and dilution. Along the way, the company is building institutional relationships from its retail base established in their home country and here too. We are not concerned about the transition we see ahead (retail to institutional), which we believe is data-driven, exactly as it was for the CAR-T companies like Kite (KITE-Not rated), Juno (JUNO-Not rated) and BlueBird (BLUE Not Rated).

Partnerships. The most recent addition to Mesoblast's ever-growing list of partnerships is Grunenthal (ALM-Spain – Not rated) for Europe & Latin America. Roughly Grunenthal agreed to $150M in upfront payments and milestones ($45M in year one with $15M on signing) for DDD indication. The deal follows the Tasly Pharmaceuticals (600535-Shanhai – Not Rated) partnership for China. Back in 2011 a manufacturing partnership with Lonza (facility is on the ground in Singapore) and in 2010, the first partnership with cephalon (CEPH-Not Rated, acquired by Teva-Teva Not rated) which supported the CHF program until Teva as (in our opinion), as result of Teva's own internal chaos, terminated the partnership relinquishing all rights after investing millions and initiating the pivotal CHF program.

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.

How is the Remestemcel-L COVID-19 ARDS Program Progressing ? *From Mesoblast*;

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 will randomize 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 ($2x10^6$ 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 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[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)	(67)	(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	2030E											
NPV Per Share	$ 20												

Source: Dawson James estimates, company reports

Exhibit 5. Discounted-EPS Model

		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%
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

Earnings Multiple

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 MM's	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																
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 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 & Adminastration	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.

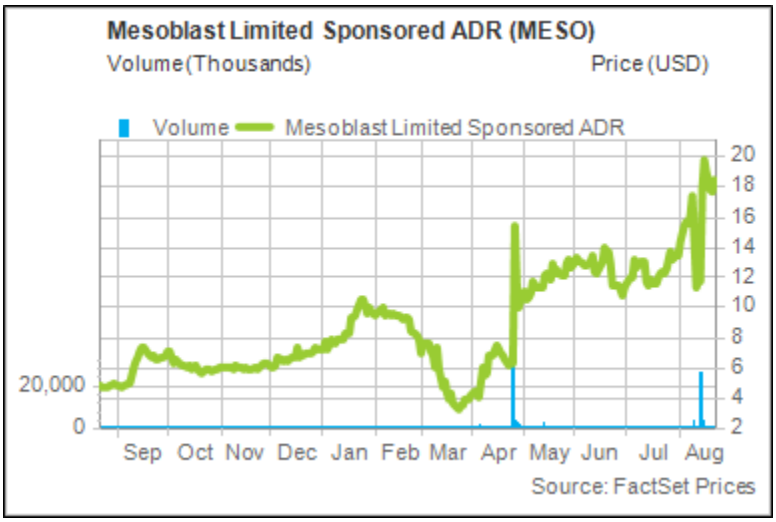
Partnership risk. Mesoblast may seek partnerships for clinical development support and commercialization. We have no specific knowledge of any discussions with possible partners today, and there can be no assurances that the company will be able to secure a favorable partnership.

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
Grunethal
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

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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) **Neutra**l: The analyst believes the price of the stock is fairly valued for the next 12-18 months;
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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.

	Company Coverage		Investment Banking	
Ratings Distribution	# 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%

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