

Athersys Inc. (NASDAQ/ATHX) Buy-Rated

December 21, 2020

Differences: MultiStem Vs. Remestemcel

Recall that Mesoblast (MESO-Buy Rated) reported last week that the company's trial in COVID-ARDS was not likely to reach statistical significance. In the past year, new therapies developed for COVID have improved the standard of care so much that Mesoblast's trial is not likely to reach its goal. This begs the question "What about Athersys MultiStem?" We "spoke" with the management of Athersys and they reminded us of some of the key differences between the products (stated below).

- **Distinct cell types** - Mesoblast uses mesenchymal stem cells (MSCs) and Athersys uses Multipotent Adult Progenitor Cells (MAPCs). According to Athersys, the MAPCs that comprise MultiStem have been shown to have superior scalability and other distinctive biological properties relative to MSCs and other cell types. Furthermore, MAPC cells obtained from a single healthy, consenting donor may be used to produce hundreds of thousands to millions of individual doses. This is in contrast to MSCs, which tend to lose potency or senesce after multiple passages. Athersys believes that competitors may face limited scalability of their MSCs.
- **Different dosing** – Mesoblast doses (IV) at ~2 Million cells / kg body weight, which generally translates to a dose of approximately 150 million cells versus MultiStem at 1.2 billion cells – which is 8x higher.
- **Foundational and mechanistic data** – Athersys has been working in the ARDS space for years. The company believes based on this data that their cells have a different expression profile and greater therapeutic activity than traditional MSCs, which could translate to a higher effective differential, above and beyond the difference in dosing.
- **Timing of administration** – The Athersys MACOVIA (COVID-ARDS) study emphasizes early dosing (i.e., within 48 hours of ARDS diagnosis and patient ventilation). Mesoblast has been administering within 72 hours, a longer time that may lead to reduced effectiveness.

Valuation. Our therapeutic models for MultiStem do not include ARDS. We assume a probability of success (PoS) factor across the various other indications. In addition to this, we also apply a 30% risk rate (r) in our Free Cash Flow to the Firm (FCFF), discounted EPS, and Sum-Of-The-Parts (SOP) models. Our price target is derived from these three models, equally weighting and averaged to the nearest whole number. The result is a one-year price target of \$7.00 per share. We caution that models can't predict clinical trial outcomes, but we do suggest that upon success, the company is undervalued.

Risks to our thesis include the following: (1) clinical trial; (2) commercial; (3) employee; (4) financial; (5) intellectual property; (6) partnership; and (7) regulatory. We review these and other risks in the risk section of this report.

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Current Price	\$1.97
Price Target	\$7.00

Estimates	F2019A	F2020E	F2021E
Expenses (\$000s)	\$ 51,121	\$ 75,317	\$ 50,449
1Q March	\$ 14,705	\$ 15,759	\$ 11,603
2Q June	\$ 14,163	\$ 18,421	\$ 12,108
3Q September	\$ 11,981	\$ 22,404	\$ 12,612
4Q December	\$ 10,272	\$ 18,733	\$ 14,126
	F2019A	F2020E	F2021E
EPS (diluted)	\$ (0.29)	\$ (0.40)	\$ (0.22)
1Q March	\$ (0.09)	\$ (0.10)	\$ (0.05)
2Q June	\$ (0.06)	\$ (0.10)	\$ (0.05)
3Q September	\$ (0.08)	\$ (0.11)	\$ (0.05)
4Q December	\$ (0.06)	\$ (0.09)	\$ (0.06)
EBITDA/Share	(\$0.29)	(\$0.40)	(\$0.22)
EV/EBITDA (x)	1,173	861	1,596
Stock Data			
52-Week Range	\$1.13	-	\$4.38
Shares Outstanding (mil.)	197.4		
Market Capitalization (mil.)	\$389		
Enterprise Value (mil.)	\$345		
Debt to Capital	0%		
Book Value/Share	\$0.19		
Price/Book	8.4		
Average Three Months Trading Volume (K)	13,034		
Insider Ownership	10.1%		
Institutional Ownership	28.4%		
Short interest (mil.)	12.5%		
Dividend / Yield	\$0.00/0.0%		



MACOVIA. The U.S. trial is well underway and enrolling patients. The trial is an open-label, single active treatment arm planned to evaluate MultiStem at two dose levels in patients with moderate to severe ARDS associated with COVID-19. The primary efficacy endpoint for the MACOVIA study will compare the number of ventilator-free days through day 28 among MultiStem and placebo treatment groups. Secondary objectives of the study are to evaluate 60-day all-cause mortality, time in the intensive care unit, pulmonary function, tolerability, and quality of life (QoL) among survivors through one year of follow-up.

Clinical Progress Is Maturing. Athersys is working hard to complete current trials in stroke and trauma, as well as the COVID-19 ARDS trial. The goal remains to complete the MASTERS-2 study next year. Partner Healios is also working to complete the TREASURE (stroke trial) this year and its ONE-BRIDGE ARDS study.

Modeling Assumptions

1. The MultiStem program is the main platform for the company, and we view it as the driver of the company's success. We assume Athersys continues developing the MultiStem program in neurological, cardiovascular, and inflammation and immunological disease areas and that these programs, like the MultiStem platform itself, are prioritized.
2. For the stroke (neurological) indication, we model approximately 800,000 stroke patients in the U.S. and 340,000 in Japan, with 87% of those classified as ischemic, growing at a rate of 0.1% annually since 2017. By factoring in mortality risk, cortical stroke prevalence, and the effective therapeutic treatment window, we arrive at an addressable market population.
3. Hemorrhagic stroke. Success in ischemic stroke sets the stage for Athersys to develop MultiStem in the small side of the stroke market, Hemorrhagic strokes. Here too, the inflammatory response contributes to additional secondary damage. While the complexities of ischemic stroke are challenging, hemorrhagic can be even more complex, and with even fewer options for patients. As such, it makes sense to develop for this indication only after the ischemic market is realized.
4. For the ADRS (immune) indication, we model the addressable population based on the NHLI estimate figure of 70 per 100,000 in the U.S., denoting an approximate 230,000 patients in 2017 growing at 3.1% annually.
5. For the AMI (cardiovascular) indication, we only model for new heart attacks as we believe they are more likely to be amenable to the trophic and anti-inflammatory effects of MultiStem. We anticipate the annual growth rate and mortality rate quoted by the American Heart Association continue to be high, at 11.1% and 15.5%, respectively, a reflection of the increasing obesity epidemic in the U.S. Considering the lengthy nature of cardiovascular trials, we do not begin to model sales until 2022, and we currently anticipate relatively low (8-10%) peak market penetration as cell therapy is not currently a standard of care in hospitals for treating AMI.
6. For the trauma (inflammatory) indication, we model the treatable population based on a reported 2.5 million trauma-related emergency room visits. Approximately 13% of those visits are due to debilitating ailments, leading to hospitalization. The estimation brings us to over 300,000 addressable patients growing at a rate of 3.1% annually.
7. For the GVHD (inflammatory) indication, we do not currently assume any revenues in our model, but we show the model as we believe, with additional resources, Athersys may "down the road" re-visit development plans. The population of total U.S. allogeneic stem cell transplants based on 4,265 related and 4,972 unrelated transplants (2017 data) is growing at a rate of 3.1% annually. We estimate 90% of that population to desire prophylactic treatment for GVHD.
8. We model a price for MultiStem at \$25,000 initially, growing at 1% per year. Academic literature estimates that therapies such as tPA in stroke should be priced at \$45,800 based on the quality-adjusted life years (QALY) provided to patients. In this instance, should a therapy allow for successful treatment beyond the three- to six-hour therapeutic time window, the literature estimates this therapy should command a higher price. We therefore believe our pricing estimates are conservative, considering our belief in the upside therapeutic potential of MultiStem. We have seen examples of other cell (for example, CAR-T) and gene therapies command prices anywhere between \$100k and \$2.5M; given the blockbuster size of the stroke market, we recognize the therapy must be affordable for the market size.
9. But are also relatively in line with other allogeneic cell therapies currently on the market, despite the other allogeneic cell therapies not being approved for the same targeted indications.
10. Our sum-of-the-parts model uses the same probabilities as the product models and the same discount rate as the FCF. We apply a risk factor of 70% for the trauma and AMI clinical programs as they are in earlier stages (neither beyond Phase 2) and have only been tested in a limited number of patients. We anticipate reducing this risk factor should the trials meet our assumptions of producing data in the next year. For royalties and partnerships, we also use 50% because they are dependent on a third party, Healios, and therefore do not provide transparency in terms of timing of cash flows to Athersys. Lastly, the stroke and ARDS indications have a 50% risk factor as a result of the inherent variability associated with stroke and the fact that the current pivotal programs are based on a post-hoc analysis.

Valuation. Our therapeutic models for MultiStem assume a probability of success (PoS) for all the forecast therapeutic indications. We project our model through the year 2030. For modeling purposes, we use a 30% risk rate (r) in our Free Cash Flow to the Firm (FCFF), discounted EPS, and Sum-Of-The-Parts (SOP) models. Our price target is derived from these three models, equally weighted and averaged to the nearest whole number. The result is a one-year price target of \$7.00 per share.

Exhibit 7. FCFF Model

Average of Metrics	\$	7
FCFF Price Target	\$	8
Year		2020

DCF Valuation Using FCFF (mln):

units ('000)	2019A	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(45,488)	(75,146)	(50,449)	342,027	758,789	1,365,428	1,979,916	2,652,165	3,253,308	3,889,531	4,565,591	5,286,901
Tax Rate	0%	0%	0%	14%	16%	20%	24%	28%	29%	30%	31%	32%
EBIT(1-t)	(45,488)	(75,146)	(50,449)	294,143	637,383	1,092,342	1,504,736	1,909,559	2,309,848	2,722,671	3,150,258	3,595,093
CapEx	(579)	(735)	(809)	(889)	(978)	(1,076)	(1,184)	(1,302)	(1,432)	(1,576)	(1,733)	(1,906)
Depreciation	941	1,035	1,138	1,252	1,377	1,515	1,666	1,833	2,016	2,218	2,439	2,683
Change in NWC	(130)	(3,704)	-	-	-	-	-	-	-	-	-	-
FCFF	(44,997)	(71,142)	(50,119)	294,506	637,781	1,092,781	1,505,218	1,910,089	2,310,432	2,723,314	3,150,964	3,595,870
PV of FCFF	(58,495)	(71,142)	(38,553)	174,264	290,296	382,613	405,399	395,725	368,205	333,850	297,135	260,838
Discount Rate		30%										
Long Term Growth Rate		1%										
Terminal Cash Flow		12,523,547										
Terminal Value YE2030		908,435										
NPV		3,707,063										
NPV-Debt		-										
Shares out ('000)		476,695										
NPV Per Share	\$	8										

Source: Dawson James estimates, company reports

Exhibit 8. Discounted EPS Model

Current Year	2020
Year of EPS	2030
Earnings Multiple	10
Discount Factor	30%
Selected Year EPS	\$ 7.55
NPV	\$ 5.47

Discount Rate and Earnings Multiple Varies, Year is Constant							
2030 EPS							
	5.5	20%	25%	30%	35%	40%	45%
Earnings Multiple	10	\$12.19	\$8.10	\$5.47	\$3.75	\$2.61	\$ 1.84
	15	\$18.28	\$12.15	\$8.21	\$5.63	\$3.91	\$ 2.76
	20	\$24.37	\$16.21	\$10.95	\$7.51	\$5.22	\$ 3.67
	25	\$30.47	\$20.26	\$13.68	\$9.38	\$6.52	\$ 4.59
	30	\$36.56	\$24.31	\$16.42	\$11.26	\$7.83	\$ 5.51
	35	\$42.66	\$28.36	\$19.16	\$13.14	\$9.13	\$ 6.43
	40	\$48.75	\$32.41	\$21.90	\$15.01	\$10.44	\$ 7.35
	45	\$54.84	\$36.46	\$24.63	\$16.89	\$11.74	\$ 8.27

Source: Dawson James estimates

Exhibit 9. Sum of the Parts Model

Athersys Sum of the Parts	LT Gr	Discount Rate	Yrs. to Mkt	% Success	Peak Sales	Term Val
MultiStem Ischemic Stroke (U.S.)	1%	30%	3	50%	\$4,742	\$16,353
NPV						\$3.12
MultiStem Hemorrhagic Stroke (U.S.)	1%	30%	3	50%	\$1,123	\$3,872
NPV						\$0.74
MultiStem GI GVHD	1%	30%	3	50%	\$0	\$0
NPV						\$0.00
MultiStem ARDS	1%	30%	6	50%	\$766	\$2,641
NPV						\$0.23
MultiStem AMI	1%	30%	5	30%	\$5,378	\$18,546
NPV						\$1.26
MultiStem Trauma	1%	30%	6	30%	\$1,743	\$6,010
NPV						\$0.31
Net Margin						40%
MultiStem-Japan Royalties	1%	30%	3	50%	\$423	\$1,460
NPV						\$0.70
MM Shrs OS						477
						\$6.36

Source: Dawson James estimates

Risk Analysis

Clinical Risk: Athersys is an early-stage biotechnology company currently operating with high expenditures and no product revenues. A significant element of the company's valuation is associated with its lead clinical candidate MultiStem. As such, clinical progress with this stem cell product represents the key risk for the company and shareholders.

Commercial Risk: There can be no assurances that the pipeline products will be commercialized, and if they receive regulatory approval, there is a risk that Athersys will not be able to reach the projected market share potential.

Employee Risk: Athersys has an experienced management team, which plans to ideally bring MultiStem to market within the next three years. The success of the company may depend on the expertise, abilities, and continued services of its senior officers, sales staff, and key scientific personnel.

Financial Risk: Athersys has a high burn rate and is currently not a profitable company. The company might face multiple dilutions in the future to raise capital to fund its operations.

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 upon or will be held as valid if challenged, and the company may infringe on third parties' patents.

Partnership Risk: The potential benefits from the partnership with Healios are subject to certain milestones, which, if not achieved, may delay commercialization in Japan and fail to provide payments to Athersys.

Regulatory Risk: There are no assurances that Athersys's products will be approved in the U.S., Japan, Europe, or other markets.

Companies mentioned in this report:

Healios (TYO-4593: Not Rated)
 Mesoblast (MESO: Buy Rated)
 Pluristem (PSTI: Buy Rated)

Important Disclosures:

Price Chart:



Price target and rating changes over the past three years:

- Initiated – Buy – August 26, 2019 – Price Target \$11.00
- Update – Buy – November 7, 2019 – Price Target \$11.00
- Update – Buy – January 14, 2020 – Price Target \$11.00
- Update – Buy – February 11, 2020 – Price Target \$11.00
- Update – Price Target Change – March 17, 2020 – Price Target from \$11.00 to \$12.00
- Update – Buy – March 23, 2020 – Price Target \$12.00
- Update – Buy – April 9, 2020 – Price Target \$12.00
- Update – Buy – April 13, 2020 – Price Target \$12.00
- Update – Buy – April 15, 2020 – Price Target \$12.00
- Update – Buy – May 1, 2020 – Price Target \$12.00
- Update – Buy – May 5, 2020 – Price Target \$12.00
- Update – Buy – May 8, 2020 – Price Target \$12.00
- Update – Buy – June 22, 2020 – Price Target \$12.00
- Price Target Change - Buy – August 11, 2020 – Price Target \$7.00
- Update – Buy – September 23, 2020 – Price Target \$7.00
- Update – Buy – November 10, 2020 – Price Target \$7.00
- Update – Buy – November 18, 2020 – Price Target \$7.00
- Update – Buy – November 24, 2020 – Price Target \$7.00
- Update – Buy – December 21, 2020 – Price Target \$7.00

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Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	21	78%	5	24%
Market Perform (Neutral)	6	22%	1	17%
Market Underperform (Sell)	0	0%	0	0%
Total	27	100%	6	22%

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