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Athersys Inc. (NASDAQ/ATHX)

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BUY: MACOVIA – Reports the Quarter as Multistem Enrolls the First WuHan (China) Virus COVID Patient

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Athersys reports the quarter spending $15.7M in the first quarter and closing the period with $33M in cash in addition to the capital raised ($57.6M). Management reviewed the ARDS trial, having met with BARDA and other related government agencies. The trauma trial received Phase 2 authorization to move forward. The Master's Stroke trial is continuing. Partnering discussions in Europe are ongoing.

Current Price	**$2.63**
Price Target	**$12.00**

Estimates	F2019A	F2020E	F2021E
Expenses ($000s)	$ 51,121	$ 53,500	$ 46,615
1Q March	$ 14,705	$ 15,759	$ 10,721
2Q June	$ 14,163	$ 12,840	$ 11,188
3Q September	$ 11,981	$ 13,375	$ 11,654
4Q December	$ 10,272	$ 11,526	$ 13,052
	F2019A	F2020E	F2021E
EPS (diluted)	$ (0.29)	$ (0.30)	$ (0.22)
1Q March	$ (0.09)	$ (0.10)	$ (0.05)
2Q June	$ (0.06)	$ (0.08)	$ (0.05)
3Q September	$ (0.08)	$ (0.07)	$ (0.05)
4Q December	$ (0.06)	$ (0.06)	$ (0.06)
EBITDA/Share	($0.29)	($0.29)	($0.22)
EV/EBITDA (x)	1,608	1,607	2,129
Stock Data			
52-Week Range	$1.13	-	$4.38
Shares Outstanding (mil.)			196.5
Market Capitalization (mil.)			$517
Enterprise Value (mil.)			$472
Debt to Capital			0%
Book Value/Share			$0.19
Price/Book			8.4
Average Three Months Trading Volume (K)			440
Insider Ownership			11.6%
Institutional Ownership			19.6%
Short interest (mil.)			8.4%
Dividend / Yield			$0.00/0.0%

Highlights

MAGA- Make Athersys Great (again). Athersys is working hard to complete current trials in stroke, and now in Trauma as well as the new WuHan (China) Trial. The goal remains to complete the Master's 2 study next year. Partner Healios is also working to complete the TREASURE (Stroke trial) this year and its ONE-BRIDGE ARDS study which will now include WuHan Virus patients in Japan.

COVID19 – China Virus: Athersys announced that UHC has now enrolled its first COVIOD patient in the first cohort of the study. 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. If the treatment is well tolerated in this first cohort, the study is designed to further evaluate MultiStem efficacy, safety, and tolerability in this patient population using a robustly powered, double-blind, randomized, and placebo-controlled trial protocol. 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.

Athersys raises Capital. A recent public offering transpired consisting of 25.5M shares of common stock at a price to the public of $2.25 per share, which includes 3,337,500 shares of Common Stock pursuant to the underwriters' option to purchase additional shares, which the underwriters exercised (April 16, 2020). Gross proceeds to Athersys from the offering are approximately $57.6 million, before deducting the underwriting discount and estimated offering expenses. Our model previously assumed dilution, and as such, this raise has no impact on our valuation metrics. Combined with reported capital Athersys now has > $80M in cash runway.

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 Some-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 $12.00 per share. We caution ourselves that models can't predict clinical trial outcomes, but we do suggest that upon success, the company is undervalued.

We Believe. Athersys' Multistem offers great hope for patients suffering from Acute Respiratory Distress Syndrome (ARDS). ARDS occurs when fluid builds up in the tiny, elastic air sacs (alveoli) in your lungs. Severe pneumonia and the new Coronavirus, too, can result in an infection in the lobes of the lungs, triggering an inflammatory cascade that causes death. Data on Athersys Multistem suggest efficacy in treating ARDS independent of the pathogen (or insult) that is the cause.

Highlights *(from Athersys Press Release)*:

- Received authorization from the U.S. Food and Drug Administration (FDA) to initiate a Phase 2/3 COVID-19 induced acute respiratory distress syndrome (ARDS) clinical trial; completed site initiation and began enrolling patients in this trial referred to as the MACOVIA study;
- Received FDA authorization to initiate a Phase 2 clinical trial with The University of Texas Health Science Center at Houston (UTHealth) titled MultiStem® Administration for Trauma Related Inflammation and Complications (MATRICS-1); funded by a grant from the Medical Technology Enterprise Consortium (MTEC) and the Memorial Hermann Foundation;
- Announced positive one-year results from our exploratory clinical study of MultiStem cell therapy for ARDS; MultiStem treated patients reported consistent improvement in quality of life over the one-year evaluation period and showed marked improvements in key clinical metrics, including intensive care unit-free days, ventilator-free days and mortality compared to placebo, especially in patients with pneumonia-induced ARDS;
- Furthered discussions with the Biomedical Advanced Research and Development Authority (BARDA) to establish a collaboration to advance our MultiStem program;
- Appointed Mr. Ivor Macleod as our Chief Financial Officer and Ms. Maia Hansen as Senior Vice President, Operations and Supply Chain, adding their expertise to our leadership team to help plan and execute our strategy as we approach potential product commercialization;
- Initiated new sites for the MASTERS-2 ischemic stroke study while continuing to enroll new patients into the trial;
- Advanced through our Japanese partner, HEALIOS K.K. (Healios), its ARDS and ischemic stroke programs, with Healios disclosing its intent to finish enrollment of both its ONE-BRIDGE ARDS study and its TREASURE stroke study this year;
- Engaged in partnering discussions with companies interested in MultiStem commercialization rights in Europe and other regions;
- Received an additional $7.0 million investment from Healios resulting from its exercise in full of a warrant to purchase additional shares of Athersys common stock;
- Raised gross proceeds of approximately $57.6 million, before deducting the underwriting discount and offering expenses, through an underwritten public offering of 25,587,500 shares of common stock, providing additional working capital for general corporate purposes, including the initiation of the MACOVIA trial, further advancement of process development and manufacturing projects, and other key initiatives;
- Recognized net loss of $15.6 million, or $0.10 net loss per share, for the quarter ended March 31, 2020; and
- Ended the first quarter with $32.7 million of cash and cash equivalents, which excludes the impact of the Healios warrant exercise and proceeds from the recent underwritten public offering.

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.

COVID ARDS Trial Design: The trial is planned as a multicenter study featuring an open-label lead-in followed by a double-blinded, randomized, placebo-controlled Phase 2/3 portion. The primary objectives of the MACOVIA study is to evaluate the safety and efficacy of MultiStem therapy as a treatment for subjects with moderate to severe ARDS due to COVID-19.

- The primary efficacy endpoint will be number of ventilator-free days through day 28 as compared to placebo, a well-established endpoint for ARDS trials that evaluates an intervention's combined impact on survival and liberation from invasive mechanical ventilation.
- The secondary objectives of this study are to evaluate pulmonary function, all-cause mortality, tolerability and quality of life (QoL) among survivors associated with MultiStem therapy as a treatment for subjects with moderate to severe ARDS due to COVID-19. The study is designed to enroll approximately 400 subjects and will be conducted at leading pulmonary critical care centers throughout the U.S. The first cohort of the study will be open-label, with a single active treatment arm to evaluate the safety of the MultiStem product candidate at two dose levels. The second cohort will be a double-blind, randomized, placebo-controlled run-in phase to evaluate the efficacy of MultiStem. The design of the third planned cohort will be based on analysis of the results of the second cohort. The intent-to-treat population will include all randomized subjects (i.e., subjects from the second and third cohorts).

We Review Multistem's Prior Program in ARDS. A few key observations, in our opinion, make this relevant today given the Coronavirus outbreak in China and the world.

1. The data released last month is impressive for a small study and suggests that Multistem has efficacy in ARDS.
2. Multistem works independent of the cause, albeit pneumonia or the coronavirus. As such, it has the potential to be an ideal, first-line defense for patients in respiratory distress.
3. ARDs has a high mortality rate. The treatment protocols are very complex, and one look at the numbers in China tells us the potential to overwhelm the system, any system be it the U.S. or China, is a great risk.
4. ARDS is likely the factor that tips most pneumonia (& likely Coronavirus) patients to a high risk, high mortality outcome.
5. A universal treatment that can limit ARDS could be a life-saver. All indications suggest that Athersys partner Healios is keenly interested. The Japanese media and government are focused on the coronavirus. It is the number one news story in Japan and has been for weeks.
6. Early data not only suggest better outcomes at 28 days, but one-year follow-up also suggests that treated patients are more likely to reestablish the same quality of life versus control patients prior to ARDS.

Quality-of-Life (QOL) Out to a Year. Recall that Athersys announced follow-up results from the prior ARDS study of IV (intravenous) MultiStem. These participants were evaluated through 28 days for the primary clinical assessment and again at a one-year follow-up. Of note, the most severe patients seemed to do the best (20% mortality versus 50% on control).

Key Data Points from the Athersys ARDS study:

- Previously observed lower mortality for MultiStem-treated subjects compared to placebo (particularly among the prospectively defined subset of more severe ARDS patients) persisted out to one-year of follow-up;
- Day-365 Quality of Life (QoL) outcomes, assessed by the EQ-5D, were meaningfully better among all survivors who received MultiStem treatment compared to those who received placebo;
- Within the prospectively defined group of patients with more severe ARDS, MultiStem treatment was associated with a markedly greater rate of survival and progression to functional independence at one year (i.e., self-care);
- As measured at day-28, MultiStem treatment was associated with a higher mean ventilator-free day (VFD) score of 12.9 vs. 9.2 in the placebo group, and a higher mean intensive care unit (ICU)-free day score of 10.3 vs. 8.1 in the placebo group;
- As measured at day-28, among more severe ARDS patients, mean VFD in the MultiStem subgroup was 14.6 vs. 8.0 in placebo subgroup. Mean ICU-free days were 11.4 vs. 5.9 for MultiStem and placebo recipients, respectively;
- Lower inflammatory cytokine levels at day-7 in the MultiStem group relative to the placebo group, including IFNg, IL-6, and IL-1b among others, suggest the potential for MultiStem treatment to abate the severe inflammatory response associated with ARDS; and
- MultiStem treatment was well tolerated in this very sick ARDS patient population, with no serious adverse events related to administration through one year of follow-up.

Exhibit 1. The Phase 2 ARDS Trial was a randomized, double-blind, placebo-controlled trial evaluating patients through 28-day clinical assessment with one year follow up.

All Subjects	MultiStem	Placebo
Number	20	10
Ventilator-free days (mean)	12.9	9.2
(median)	**18.5**	**6.5**
ICU-free days (mean)	10.3	8.1
(median)	**12.5**	**4.5**
Mortality (d28)	25%	40%
Patients w/ Low pulmonary function: PaO_2/FiO_2 < 150 mm at baseline	**MultiStem**	**Placebo**
Number	8	8
Ventilator-free days (mean)	14.6	8.0
(median)	**18.5**	**3.5**
ICU-free days (mean)	11.4	5.9
(median)	**12.5**	**1**
Mortality (d28)	25%	50%

Source: Athersys

Exhibit 2. The Post-hoc analysis of Pneumonia-Induced ARDS, Severe cases –PaO2/FiO2Ratios at Day 0, Pre-infusion < 150. Data for severe cases of pneumonia-induced ARDS shows an even greater difference in mortality rate, Vent-free, and ICU-free days between the subjects treated with MultiStem and the patients in the placebo-controlled group.

	MultiStem	Placebo
Day-28 Mortality	20%	50%
Ventilator-free days (mean)	14.8	7.5
Ventilator-free days (median)	**18.0**	**3.5**
ICU-free days (mean)	12.0	5.0
ICU-free days (median)	**15.0**	**1.0**

Source: Athersys

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 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) 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 FCFF. 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.
11. Discount rate. We use a 30% discount rate to account for the fact that Athersys is not yet a profitable company, with assets still in clinical development and several years from commercialization. For this reason, we add an additional risk premium to the calculated WACC to arrive at our 30% discount rate.

Exhibit 3. MultiStem Ischemic Stroke (U.S.).

Ischemic Stroke (U.S.)	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
No. of Annual Strokes	696,000	696,696	697,393	698,090	698,788	699,487	700,186	700,887	701,588	702,289	702,991	703,694	704,398	705,102
Market Size Growth	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Associated Mortality	16.3%	16.3%	16.3%	16.3%	16.3%	16.3%	16.3%	16.3%	16.3%	16.3%	16.3%	16.3%	16.3%	16.3%
Ischemic Strokes Survivors	582,552	583,135	583,718	584,301	584,886	585,471	586,056	586,642	587,229	587,816	588,404	588,992	589,581	590,171
Total cortical ischemic stroke patients (35%)	203,893	204,097	204,301	204,505	204,710	204,915	205,120	205,325	205,530	205,736	205,941	206,147	206,353	206,560
Market Share Penetration	0%	0%	0%	0%	0%	5%	10%	15%	20%	25%	30%	35%	40%	45%
Number of Patients Procedures	-	-	-	-	-	29,274	58,606	87,996	117,446	146,954	176,521	206,147	235,832	265,577
Cost of Therapy						$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000
Risk Factor						50%	50%	50%	50%	50%	50%	50%	50%	50%
Total Revenue ('000)						**$ 365,919**	**$ 732,570**	**$1,099,954**	**$1,468,072**	**$1,836,925**	**$2,206,514**	**$2,576,841**	**$2,947,906**	**$3,319,711**

Source: Dawson James estimates.

Exhibit 4. MultiStem Ischemic Stroke (Japan).

Ischemic Stroke (Japan)	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
No. of Annual Strokes	295,800	296,096	296,392	296,688	296,985	297,282	297,579	297,877	298,175	298,473	298,771	299,070	299,369	299,669
Market Size Growth	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Associated Mortality	16.3%	16.3%	16.3%	16.3%	16.3%	16.3%	16.3%	16.3%	16.3%	16.3%	16.3%	16.3%	16.3%	16.3%
Ischemic Strokes Survivors	247,585	247,832	248,080	248,328	248,576	248,825	249,074	249,323	249,572	249,822	250,072	250,322	250,572	250,823
Total cortical ischemic stroke patients (35%)	86,655	86,741	86,828	86,915	87,002	87,089	87,176	87,263	87,350	87,438	87,525	87,613	87,700	87,788
Market Share Penetration	0%	0%	0%	0%	0%	5%	10%	15%	20%	25%	30%	35%	40%	45%
Number of Patients Procedures	-	-	-	-	-	12,441	24,907	37,398	49,914	62,455	75,021	87,613	100,229	112,870
Cost of Therapy						$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000
Risk Factor						50%	50%	50%	50%	50%	50%	50%	50%	50%
Japan Annual Sales						**$ 155,516**	**$ 311,342**	**$ 467,480**	**$ 623,931**	**$ 780,693**	**$ 937,769**	**$1,095,157**	**$1,252,860**	**$1,410,877**
Royalty to Athersys						8%	10%	12%	14%	15%	15%	15%	15%	15%
Total Revenue ('000)						**$ 12,441**	**$ 31,134**	**$ 56,098**	**$ 87,350**	**$ 117,104**	**$ 140,665**	**$ 164,274**	**$ 187,929**	**$ 211,632**

Source: Dawson James estimates.

Exhibit 5. MultiStem Hemorrhagic Stroke (U.S.)

Hemorrhagic Stroke (U.S.)	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
No. of Annual Hem. Strokes (13% of total)	90,480	90,570	90,661	90,752	90,842	90,933	91,024	91,115	91,206	91,298	91,389	91,480	91,572	91,663
Market Size Growth	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Associated Mortality	30.0%	30.0%	30.0%	30.0%	30.0%	30.0%	30.0%	30.0%	30.0%	30.0%	30.0%	30.0%	30.0%	30.0%
Hemorrhagic Strokes Survivors	63,336	63,399	63,463	63,526	63,590	63,653	63,717	63,781	63,844	63,908	63,972	64,036	64,100	64,164
Market Share Penetration	0%	0%	0%	0%	0%	0%	0%	15%	30%	50%	55%	60%	65%	70%
Number of Patients Procedures	-	-	-	-	-	-	-	9,567	19,153	31,954	35,185	38,422	41,665	44,915
Cost of Therapy							$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000
Risk Factor							50%	50%	50%	50%	50%	50%	50%	50%
Total Revenue ('000)						**$ -**	**$ -**	**$ 119,589**	**$ 239,417**	**$ 399,427**	**$ 439,809**	**$ 480,271**	**$ 520,814**	**$ 561,438**

Source: Dawson James estimates.

Exhibit 6. MultiStem Acute Respiratory Distress Syndrome (U.S.).

Acute Respiratory Distress Syndrome (U.S.)	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
No. of Annual Cases	228900	235,996	243,312	250,854	258,631	266,648	274,915	283,437	292,223	301,282	310,622	320,251	330,179	340,415
Market Size Growth	3.1%	3.1%	3.1%	3.1%	3.1%	3.1%	3.1%	3.1%	3.1%	3.1%	3.1%	3.1%	3.1%	3.1%
Market Share Penetration			0.0%	0.0%	0.0%	1%	2%	3%	4%	5%	6%	7%	8%	9%
Number of Patients Procedures			-	-	-	2,666	5,498	8,503	11,689	15,064	18,637	22,418	26,414	30,637
Cost of Therapy						$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000
Risk adjustment						50%	50%	50%	50%	50%	50%	50%	50%	50%
Total Revenue ('000)						**$ 33,331**	**$ 68,729**	**$ 106,289**	**$ 146,112**	**$ 188,302**	**$ 232,967**	**$ 280,220**	**$ 330,179**	**$ 382,967**

Source: Dawson James estimates.

Exhibit 7. MultiStem Acute Myocardial Infarction (U.S.).

Acute Myocardial Infarction (U.S.)	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
No. of Annual Heart Attacks	720,000	799,920	888,711	987,358	1,096,955	1,218,717	1,353,994	1,504,288	1,671,264	1,856,774	2,062,876	2,291,855	2,546,251	2,828,885
Market Size Growth	11.1%	11.1%	11.1%	11.1%	11.1%	11.1%	11.1%	11.1%	11.1%	11.1%	11.1%	11.1%	11.1%	11.1%
Associated Mortality			15.5%	15.5%	15.5%	15.5%	15.5%	15.5%	15.5%	15.5%	15.5%	15.5%	15.5%	15.5%
AMI Survivors			750,961	834,318	926,927	1,029,816	1,144,125	1,271,123	1,412,218	1,568,974	1,743,130	1,936,618	2,151,582	2,390,408
Market Share Penetration			0%	0%	0%	1%	2%	3%	4%	5%	6%	7%	8%	9%
Number of Patients Procedures			-	-	-	10,298	22,883	38,134	56,489	78,449	104,588	135,563	172,127	215,137
Cost of Therapy						$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000
Risk adjustment						70%	70%	70%	70%	70%	70%	70%	70%	70%
Total Revenue ('000)						**$ 77,236**	**$ 171,619**	**$ 286,003**	**$ 423,665**	**$ 588,365**	**$ 784,409**	**$1,016,724**	**$1,290,949**	**$1,613,525**

Source: Dawson James estimate.

Exhibit 8. Trauma (U.S.).

Trauma (U.S.)	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Trauma Prevelance	2,500,000	2,577,500	2,657,403	2,739,782	2,824,715	2,912,281	3,002,562	3,095,642	3,191,606	3,290,546	3,392,553	3,497,722	3,606,152	3,717,942
Market Size Growth	3.1%	3.1%	3.1%	3.1%	3.1%	3.1%	3.1%	3.1%	3.1%	3.1%	3.1%	3.1%	3.1%	3.1%
% of Patients Hospitalized	13%	13%	13%	13%	13%	13%	13%	13%	13%	13%	13%	13%	13%	13%
Treatable Population	312,500	322,188	332,175	342,473	353,089	364,035	375,320	386,955	398,951	411,318	424,069	437,215	450,769	464,743
Market Share Penetration			0%	0%	0%	0%	1%	3%	5%	7%	9%	11%	13%	15%
Number of Patients Procedures			-	-	-	-	3,753	11,609	19,948	28,792	38,166	48,094	58,600	69,711
Cost of Therapy							$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000
Risk adjustment						70%	70%	70%	70%	70%	70%	70%	70%	70%
Total Revenue ('000)							**$ 28,149**	**$ 87,065**	**$ 149,607**	**$ 215,942**	**$ 286,247**	**$ 360,703**	**$ 439,500**	**$ 522,836**

Source: Dawson James estimates.

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 Some-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 $12.00 per share.

Exhibit 9. FCFF Model.

Average of Metrics	$	12
FCFF Price Target	$	14
Year		2020

DCF Valuation Using FCFF (mln):

units ('000)	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(45,488)	(53,484)	(46,598)	345,916	762,717	1,369,395	1,983,922	2,656,212	3,257,395	3,893,659	4,569,761	5,291,113
Tax Rate	0%	0%	0%	14%	16%	20%	24%	28%	29%	30%	31%	32%
EBIT(1-t)	(45,488)	(53,484)	(46,598)	297,488	640,682	1,095,516	1,507,781	1,912,473	2,312,750	2,725,561	3,153,135	3,597,957
CapEx	(579)	(637)	(701)	(771)	(848)	(932)	(1,026)	(1,128)	(1,241)	(1,365)	(1,502)	(1,652)
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)	-	-	-	-	-	-	-	-	-	-	-
FCFF	(44,997)	(53,086)	(46,161)	297,969	641,211	1,096,098	1,508,422	1,913,177	2,313,525	2,726,414	3,154,073	3,598,988
PV of FCFF	(58,495)	(53,086)	(35,508)	176,313	291,858	383,774	406,262	396,365	368,698	334,230	297,428	261,064

Discount Rate	30%	
Long Term Growth Rate	1%	
Terminal Cash Flow	12,534,406	
Terminal Value YE2030	909,223	
NPV	3,678,124	
NPV-Debt	-	
Shares out ('000)	265,686	
NPV Per Share	$ 14	

Source: Dawson James estimates.

Exhibit 10. Discounted EPS Model.

Current Year		2020
Year of EPS		2030
Earnings Multiple		15
Discount Factor		30%
Selected Year EPS	$	8.45
NPV	$	9.19

	Discount Rate and Earnings Multiple Varies, Year is Constant 2030 EPS					
Earnings Multiple	9.2	20%	25%	30%	35%	40%	45%
	10	$13.64	$9.07	$6.13	$4.20	$2.92	$ 2.06
	15	$20.46	$13.60	$9.19	$6.30	$4.38	$ 3.08
	20	$27.28	$18.14	$12.25	$8.40	$5.84	$ 4.11
	25	$34.11	$22.67	$15.32	$10.50	$7.30	$ 5.14
	30	$40.93	$27.21	$18.38	$12.60	$8.76	$ 6.17
	35	$47.75	$31.74	$21.45	$14.70	$10.22	$ 7.20
	40	$54.57	$36.28	$24.51	$16.80	$11.68	$ 8.22
	45	$61.39	$40.81	$27.57	$18.90	$13.14	$ 9.25

Source: Dawson James estimates.

Exhibit 11. 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						$5.60
MultiStem Hemmorhhaagic Stroke (U..S	1%	30%	3	50%	$1,123	$3,872
NPV						$1.33
MultiStem GI GVHD	1%	30%	3	50%	$0	$0
NPV						$0.00
MultiStem ARDS	1%	30%	6	50%	$766	$2,641
NPV						$0.41
MultiStem AMI	1%	30%	5	30%	$5,378	$18,546
NPV						$2.26
MultiStem Trauma	1%	30%	6	30%	$1,743	$6,010
NPV						$0.56
Net Margin						40%
MusltiStem-Japan Royalties	1%	30%	3	50%	$423	$1,460
NPV						$1.25
MM Shrs OS						266
						$11.41

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 party's 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' products will be approved in the U.S., Japan, Europe, or other markets.

Exhibit 12. Income Statement.

Athersys, Inc. Income Statement ($ '000)	BI	BN	BS	BX	CC	CH	CM	CR	CW	DB	DG	DL	DQ
ATHX: YE Dec. 31	2018A	2019A	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Product Revenue (000's)													
MultiStem Ischemic Stroke (U.S.)					365,919	732,570	1,099,954	1,468,072	1,836,925	2,206,514	2,576,841	2,947,906	3,319,711
% Chg													
MultiStem Ischemic Stroke (Japan) - Royalty					12,441	31,134	56,098	87,350	117,104	140,665	164,274	187,929	211,632
% Chg													
MultiStem Hemmorhhaagic Stroke (U..S.)					-	-	119,589	239,417	399,427	439,809	480,271	520,814	561,438
% Chg													
MultiStem ARDS					33,331	68,729	106,289	146,112	188,302	232,967	280,220	330,179	382,967
% Chg													
MultiStem AMI					77,236	171,619	286,003	423,665	588,365	784,409	1,016,724	1,290,949	1,613,525
% Chg													
MultiStem Trauma						28,149	87,065	149,607	215,942	286,247	360,703	439,500	522,836
% Chg													
Total Revenues (Product Sales, Grants & Milestones)	-	-	-	-	488,928	1,004,052	1,754,997	2,514,223	3,346,065	4,090,610	4,879,033	5,717,278	6,612,108
Contract revenues from Healios	22,276	5,517											
% Chg													
License Fees - Contract revenues	1,461	-	-	-	-	-	-	-	-	-	-	-	-
% Chg													
Grant Revenues	554	116	-	-	-	-	-	-	-	-	-	-	-
% Chg													
Pfizer Milestones													
% Chg													
Total Revenues (Product Sales, Grants & Milestones)	24,291	5,633	-	-	488,928	1,004,052	1,754,997	2,514,223	3,346,065	4,090,610	4,879,033	5,717,278	6,612,108
Expenses													
COGS (excludes royalties)	-	-	-	-	95,297	194,584	339,780	485,374	645,792	789,989	942,952	1,105,870	1,280,095
COGS % Product Sales		20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
R&D	38,656	39,045	42,000	35,000	36,000	34,920	33,872	32,856	31,871	30,914	29,987	29,087	28,215
R&D % Rev's													
G&A	10,442	11,378	11,500	11,615	11,731	11,848	11,967	12,087	12,207	12,330	12,453	12,577	12,703
G&A % Rev's													
Other (depreciation)	855	698											
Total expenses	49,953	51,121	53,500	46,615	143,028	241,352	385,619	530,317	689,870	833,233	985,392	1,147,534	1,321,013
Oper. Inc. (Loss)	(25,662)	(45,488)	(53,500)	(46,615)	345,899	762,700	1,369,378	1,983,905	2,656,195	3,257,377	3,893,641	4,569,743	5,291,094
Gain from sale of insurance proceeds, net	617												
Oper. Inc. (Loss)	(25,045)												
Oper Margin	NM	NM	NM	NM	71%	76%	78%	79%	79%	80%	80%	80%	80%
Other Income Expense (net)	762	906											
Other Income (loss of unconsolidated affiliate													
Equity Earnings (loss) of unconsolidated affiliate													
Expense from change in fair value of warrants, net													
Preferred Stock Dividends													
Change in Warrant valuation													
Deemed dividend resulting from induced conversion of convert p.stock													
Pre-tax income	(24,283)	(44,582)	(53,385)	(46,615)	345,899	762,700	1,369,378	1,983,905	2,656,195	3,257,377	3,893,641	4,569,743	5,291,094
Taxes	-	-	-	-	48,426	122,032	273,876	476,137	743,734	944,639	1,168,092	1,416,620	1,693,150
Tax Rate	0%	0%	0%	0%	14%	16%	20%	24%	28%	29%	30%	31%	32%
Net Income	(24,283)	(44,582)	(53,385)	(46,615)	297,473	640,668	1,095,502	1,507,768	1,912,460	2,312,738	2,725,549	3,153,123	3,597,944
Net Margin	NM	NM	NM	NM	61%	64%	62%	60%	57%	57%	56%	55%	54%
EPS	(0.18)	(0.29)	(0.30)	(0.22)	1.31	2.60	4.11	5.22	6.12	6.84	7.45	7.96	8.39
Non GAAP EPS (dil)	(0.16)	(0.27)	(0.28)	(0.20)	1.32	2.62	4.12	5.24	6.14	6.85	7.46	7.97	8.40
Wgtd Avg Shrs (Bas) - '000s	136,641	151,696	181,532	204,146	210,337	216,716	223,288	230,059	237,036	244,225	251,631	259,262	267,125
Wgtd Avg Shrs (Dil) - '000s	136,641	151,696	181,532	210,063	227,379	246,122	266,410	288,371	312,142	337,872	365,724	395,871	428,504

Source: Dawson James estimates.

Companies mentioned in this report:

Healios (TYO-4593: Not 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

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3) **Sel**l: The analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

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	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	22	92%	3	14%
Market Perform (Neutral)	2	8%	1	50%
Market Underperform (Sell)	0	0%	0	0%
Total	24	100%	4	17%

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