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Athersys Inc. (NASDAQ/ATHX) Buy-Rated

February 17, 2021

Management Transitions with an Eye to Commercialization

Athersys announced the departure of Gil Van Bokkelen, CEO and Founder, as the company begins the process of shifting its focus towards commercialization, pending the outcome of the company's two pivotal trials in Stroke. We take careful note that partner Healios (TYO: 4593-Not Rated) is onboard with this transition and has agreed to a stand-still provision (preventing Healios from acquiring Athersys). We view these developments as positive for the company.

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Current Price	\$2.72
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)	1,676	1,231	2,281

Stock Data			
52-Week Range	\$1.13	-	\$4.38
Shares Outstanding (mil.)	197.7		
Market Capitalization (mil.)	\$537		
Enterprise Value (mil.)	\$493		

Debt to Capital	0%
Book Value/Share	\$0.19
Price/Book	8.4
Average Three Months Trading Volume (K)	984
Insider Ownership	10.0%
Institutional Ownership	29.6%
Short interest (mil.)	12.3%
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.

What about COVID? 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.

Last Quarter's (3Q20) Results: Athersys spent \$18.4M in R&D (driven by clinical costs), combined with SG&A for a net loss of \$22M, leaving the company with approximately \$61.7M in cash. In our opinion, plenty of runway through the next series of events. There continued to be discussions about additional partners (potentially Europe), which could bring in resources.

Valuation. Our therapeutic models 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.

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 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.

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	\$	9
Year		2021

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)	253,573	662,650	1,260,816	1,865,960	2,527,898	3,117,658	3,741,308	4,403,479	5,109,435
Tax Rate	0%	0%	0%	14%	16%	20%	24%	28%	29%	30%	31%	32%
EBIT(1-t)	(45,488)	(75,146)	(50,449)	218,073	556,626	1,008,653	1,418,130	1,820,087	2,213,537	2,618,916	3,038,400	3,474,416
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)	218,435	557,025	1,009,092	1,418,612	1,820,617	2,214,121	2,619,558	3,039,107	3,475,193
PV of FCFF	(76,044)	(92,485)	(50,119)	168,027	329,600	459,304	496,696	490,345	458,713	417,469	372,562	327,709
Discount Rate	30%											
Long Term Growth Rate	1%											
Terminal Cash Flow	12,103,258											
Terminal Value YE2030	1,141,332											
NPV	4,519,155											
NPV-Debt	-											
Shares out ('000)	476,695											
NPV Per Share	\$ 9											

Source: Dawson James estimates, company reports

Exhibit 8. Discounted EPS Model

Current Year	2021
Year of EPS	2030
Earnings Multiple	10
Discount Factor	30%
Selected Year EPS	\$ 7.29
NPV	\$ 6.88

Discount Rate and Earnings Multiple Varies, Year is Constant							
2030 EPS							
	6.9	20%	25%	30%	35%	40%	45%
Earnings Multiple	10	\$14.13	\$9.79	\$6.88	\$4.90	\$3.53	\$ 2.57
	15	\$21.20	\$14.68	\$10.32	\$7.35	\$5.29	\$ 3.86
	20	\$28.27	\$19.58	\$13.75	\$9.79	\$7.06	\$ 5.15
	25	\$35.34	\$24.47	\$17.19	\$12.24	\$8.82	\$ 6.43
	30	\$42.40	\$29.37	\$20.63	\$14.69	\$10.59	\$ 7.72
	35	\$49.47	\$34.26	\$24.07	\$17.14	\$12.35	\$ 9.01
	40	\$56.54	\$39.15	\$27.51	\$19.59	\$14.12	\$ 10.30
	45	\$63.61	\$44.05	\$30.95	\$22.04	\$15.88	\$ 11.58

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%	\$681	\$2,348
NPV						\$0.20
MultiStem AML	1%	30%	5	30%	\$4,781	\$16,486
NPV						\$1.12
MultiStem Trauma	1%	30%	6	30%	\$1,743	\$6,010
NPV						\$0.31
Net Margin						40%
MuslitiStem-Japan Royalties	1%	30%	3	50%	\$423	\$1,460
NPV						\$0.70
MM Shrs OS						477
						\$6.19

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.

Exhibit 10. Income Statement.

Athersys, Inc. Income Statement (\$ '000)	BI	BN																			
ATHX: YE Dec. 31	2018A	2019A	1Q20A	2Q20A	3Q20A	4Q20E	2020E	1Q21E	2Q21E	3Q21E	4Q21E	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 Hemmorrhagic Stroke (U.S.)													-	-	119,589	239,417	399,427	439,809	480,271	520,814	561,438
% Chg																					
MultiStem ARDS													-	34,364	70,859	109,584	150,641	194,139	240,189	288,907	340,415
% Chg																					
MultiStem AMI													-	85,809	190,668	317,749	470,692	653,674	871,478	1,129,581	1,434,245
% Chg																					
MultiStem Trauma															28,149	87,065	149,607	215,942	286,247	360,703	439,500
% Chg																					
Total Revenues (Product Sales, Grants & Milestones)	-	-	-	-	-	-	-	-	-	-	-	-	378,360	883,878	1,624,233	2,371,778	3,190,731	3,921,048	4,693,755	5,514,637	6,390,275
Contract revenues from Healios	22,276	5,517		77	85																
% Chg																					
License Fees - Contract revenues	1,461	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
% Chg																					
Grant Revenues	554	116		7	1	1	9	-	-	-	-	-	-	-	-	-	-	-	-	-	-
% Chg																					
Pfizer Milestones																					
% Chg																					
Total Revenues (Product Sales, Grants & Milestones)	24,291	5,633	-	84	86	1	9	-	-	-	-	-	378,360	883,878	1,624,233	2,371,778	3,190,731	3,921,048	4,693,755	5,514,637	6,390,275
Expenses																					
COGS (excludes royalties)	-	-	-	-	-	-	-	-	-	-	-	-	73,184	170,549	313,627	456,886	614,725	756,077	905,896	1,065,342	1,235,729
COGS % Product Sales			20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
R&D	38,656	39,045	12,095	13,767	18,471	15,000	59,333	8,050	8,400	8,750	9,800	35,000	36,000	34,920	33,872	32,856	31,871	30,914	29,987	29,087	28,215
R&D % Revs																					
G&A	10,442	11,378	3,664	4,432	3,700	3,500	15,296	3,553	3,708	3,862	4,326	15,449	15,603	15,759	15,917	16,076	16,237	16,399	16,563	16,729	16,896
G&A % Revs																					
Other (depreciation)	855	698		222	233	233	688	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total expenses	49,953	51,121	15,759	18,421	22,404	18,733	75,317	11,603	12,108	12,612	14,126	50,449	124,787	221,228	363,417	505,818	662,833	803,390	952,447	1,111,158	1,280,840
Oper. Inc. (Loss)	(25,662)	(45,488)	(15,759)	(18,337)	(22,318)	(18,732)	(75,146)	(11,603)	(12,108)	(12,612)	(14,126)	(50,449)	253,573	662,650	1,260,816	1,865,960	2,527,898	3,117,658	3,741,308	4,403,479	5,109,435
Gain from sale of insurance proceeds, net	617																				
Oper. Inc. (Loss)	(25,045)																				
Oper Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	67%	75%	78%	79%	79%	80%	80%	80%	80%
Other Income Expense (net)	762	906	115	(35)	(225)																
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)	(15,644)	(18,372)	(22,543)	(18,732)	(75,291)	(11,603)	(12,108)	(12,612)	(14,126)	(50,449)	253,573	662,650	1,260,816	1,865,960	2,527,898	3,117,658	3,741,308	4,403,479	5,109,435
Taxes													35,500	106,024	252,163	447,830	707,812	904,121	1,122,393	1,365,078	1,635,019
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	14%	16%	20%	24%	28%	29%	30%	31%	32%
Net Income	(24,283)	(44,582)	(15,644)	(18,372)	(22,543)	(18,732)	(75,291)	(11,603)	(12,108)	(12,612)	(14,126)	(50,449)	218,073	556,626	1,008,653	1,418,130	1,820,087	2,213,537	2,618,916	3,038,400	3,474,416
Net Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	58%	63%	62%	60%	57%	56%	56%	55%	54%
EPS	(0.18)	(0.29)	(0.10)	(0.10)	(0.11)	(0.09)	(0.40)	(0.05)	(0.05)	(0.05)	(0.06)	(0.22)	0.86	2.03	3.40	4.42	5.24	5.88	6.43	6.89	7.28
Non GAAP EPS (dil)	(0.16)	(0.27)	(0.09)	(0.09)	(0.11)	(0.09)	(0.38)	(0.05)	(0.05)	(0.05)	(0.05)	(0.20)	0.88	2.05	3.41	4.43	5.25	5.90	6.44	6.90	7.29
Wgt'd Avg Shrs (Bas) - '000s	136,641	151,696	162,715	191,317	197,343	201,290	188,166	226,792	229,060	230,205	231,356	229,353	236,309	243,475	250,859	258,467	266,305	274,381	282,702	291,276	300,109
Wgt'd Avg Shrs (Dil) - '000s	136,641	151,696	162,715	191,317	197,343	201,290	188,166	226,792	231,328	235,954	240,673	233,687	252,950	273,801	296,372	320,802	347,246	375,871	406,855	440,393	476,695

Source: Dawson James estimates, company reports

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
- 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
- Update – Buy – February 17, 2021 – Price Target \$7.00

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- 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.

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Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	21	72%	6	29%
Market Perform (Neutral)	8	28%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	29	100%	6	21%

Analyst Certification:

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