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Athersys Inc. (NASDAQ/ATHX); Buy Rated

June 10, 2022

Management Exits – Can Athersys Survive? Increasing the Risk in Stroke Which Further Reduces our Price Target: $5.0 to $3.0

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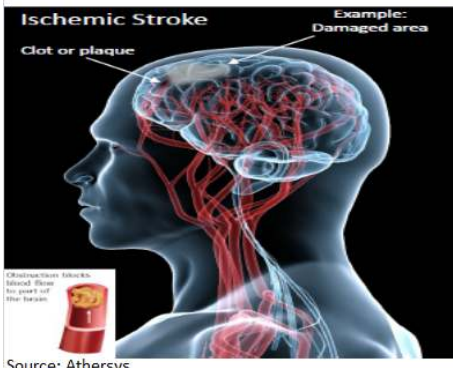
We increase our risk associated with the company's programs in Stroke from 50% to 75%, just a 25% probability of success. We also assume the company raises capital with associated dilution. The net effect is our valuation target falls from $5.0 to $3.0. Given the fall in the stock price to just $0.37, our Buy rating remains in place. Athersys last week announced the departure of senior management with the exception of the recently hired new CEO, Dan Camardo. Athersys announces a KOL panel scheduled for Tuesday at 5:00 to review the Treasure (Japan) data by a panel of expert physicians.

Current Price	$0.37
Price Target	$3.00



Source: Athersys

Stock Data			
52-Week Range	$0.18	-	$1.81
Shares Outstanding (mil.)			257.6
Market Capitalization (mil.)			$95
Enterprise Value (mil.)			$51
Debt to Capital			0%
Book Value/Share			$0.19
Price/Book			13.4
Average Three Months Trading Volume (K)			1,043
Insider Ownership			8.1%
Institutional Ownership			22.5%
Short interest (mil.)			13.0%
Dividend / Yield			$0.00/0.0%

Highlights

On May 20, 2022, Athersys partner Healios announced results from their stroke trial in Japan. Unfortunately, the trial failed to demonstrate a statically significant difference between the active and control (placebo) arms for the primary endpoint: "Excellent Outcome" measure. Management suggested (on the call) that the "miss" may be a result of the age of patients in the Japan trial as the median patient was 78 vs. the U.S. study of 63. We spoke with management and posed a series of questions to better understand what happened with the Japan study and what it means for the true probabilities of success for the US stroke trial.

Why was "Excellent Outcome" selected by Healios as the primary endpoint? In meetings leading up to the finalization of the TREASURE protocol, PMDA expressed reluctance to accept the mRS shift analysis proposed as the primary endpoint (which is the endpoint in the US MASTERS-2 study. PMDA indicated that they were more comfortable with a dichotomous outcome measure as the primary endpoint. They were willing to accept mRS shift as a lead secondary endpoint. Healios chose Excellent Outcome, a composite dichotomous outcome measure for the primary endpoint given the effect size for this endpoint observed among the subjects dosed within 36 hours of stroke onset in the MASTERS-1 study. Please see the pages that follow for our questions and answers.

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 weighted and averaged to the nearest whole number. The result is a one-year price target of $3.00 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: (1) clinical trial; (2) commercial; (3) employee; (4) financial; (5) intellectual property; (6) partnership; and (7) regulatory.

What exactly are the parameters that make up Excellent Outcome? To achieve an Excellent Outcome, at a given time point, the patient must have all three of the following:

1. a National Institutes of Health Stroke Scale (NIHSS) score of 0 or 1,
2. a modified Rankin Scale (mRS) score of 0 or 1, and
3. a Barthel Index (BI) of 95 - 100.

The NIHSS (click here) assesses neurological impairment, including comprehension, speech, sensory, and motor deficits, and is a quantitative scale from 0 to 42, where higher numbers represent a greater degree of impairment. Examples of assessment questions include evaluating whether a patient can raise their arm, move their leg, answer questions, speak clearly, visual field, etc. For illustrative purposes, a score of 20 is considered a severe stroke, a score of 10 is a moderate stroke, and a score of 2 or 3 is a mild stroke. A score of 0 to 1 using the NIHSS is considered minimal, or no, neurological impairment.

The mRS (click here) is an ordinal scale from 0 to 6 which measures the amount of global disability resulting from the stroke. This scale is focused on evaluating overall disability level, such as by assessing whether the patient is conscious, bedridden, mobility constrained, etc. and takes into consideration the level of care required. The mRS is typically measured at time points after treatment (e.g., 30 days, 90 days or beyond) to evaluate recovery progression. A score of 0 or 1 means little to no disability.

The BI (click here) is a 100-point scale that assesses the ability of the patient to independently perform activities of daily living, or whether they require some or extensive assistance. Examples of assessment questions include evaluating whether the patient can feed themselves, walk unassisted, dress, use the bathroom on their own, bathe unassisted and engage in other activities. This scale is important, because it directly measures the patient's ability to engage in basic activities of daily living and quantifies the level of assistance required from caregivers. Scoring higher on this scale is desirable and achieving a score of 95 to 100 is considered an excellent outcome.

Same question for Global Recovery. To achieve the dichotomous outcome of Global Recovery, the patient must reach the following in all three stroke scales: mRS $\leq$2, NIHSS $\Delta \geq$75% (a 75% improvement (reduction) in NIHSS score between baseline measurement and outcome assessment timepoint) and Barthel Index $\geq$95.

Specifically how do they relate to "measures of independence"? The measures of independence assessed for the Barthel Index are the following: feeding, grooming, bathing, dressing, bowels, bladder, toilet use, ability to transfer from bed to a chair and back, mobility and ability to use stairs. A score of 95 or 100 would indicate that the patient is able to perform nearly all basic activities of daily living independently. Achieving Global Recovery indicates that not only can the patient carry out these basic life activities on their own, but also has demonstrated very substantial improvement in neurological examination findings (NIHSS $\Delta \geq$75%) and is able to look after their own affairs without assistance and live independently.

The Athersys team mentioned that some patients were not starting at a function ability of "perfect or zero". Can you further explain and validate this? That is correct. Self or caregiver report that the patient was capable of independent living prior to the onset of the stroke, consistent with a pre-morbid mRS score of 0 or 1, was an inclusion criterion for the Treasure trial. However, the Barthel Index questionnaire, to assess pre-morbid independence in basic activities of daily living, was not administered as screening for study entry. And of course, NIHSS scoring, thorough physical examination prior to the onset of the stroke, was not available at the time of study participation screening (after stroke onset). Thus, despite being the primary efficacy endpoint, we cannot be sure that patients entering the trial met the Excellent Outcome criteria prior to their incident stroke. For example, an older patient, able to live independently (mRS $\leq$1), and thus eligible to participate, might be incontinent of urine and in need of assistance climbing a flight of stairs (BI = 90). While eligible for recruitment into the trial, it would be unrealistic to expect that this patient would have the capacity to achieve the primary endpoint of Excellent Outcome, even with complete recovery to baseline function following the stroke.

How is this handled in the US trial? In MASTERS-2, the primary endpoint is mRS shift analysis. mRS shift analysis allows the comparison of the distribution of ordinal mRS outcomes between treatment groups along the entire mRS scale of disability outcomes. Rather than a dichotomous outcome measure, set at an arbitrary level of function (e.g., Excellent Outcome, Global Recovery, or mRS $\leq$2), it is a measurement of treatment effect across the entire spectrum of post-stroke functional outcomes. This endpoint permits the evaluation of the impact of an investigational treatment across the full range of disability outcomes among stroke survivors and decedents, not just those that have the most fortunate outcomes. In this manner, despite its interpretation is a bit less intuitive, it can better capture the full potential impact on quality of life and quality-of-life-year (QALY) gains provided by the therapy.

How does the powering compare between the US (The MASTERS-2 study is a global trial, with study sites so far in the U.S., U.K., Europe, Taiwan, and Australia) versus the Japan Trial? What is the assumed effect for creating the powering assumptions for the US trial?

TREASURE: Powering for Excellent Outcome in the TREASURE study was based on the treatment effect for Excellent Outcome observed in the MASTERS-1 trial, among recipients of MultiStem within 36 hours of stroke onset, compared with all placebo recipients. With this assumed treatment effect, 90% power with a significance level of 5% could be achieved with 100 evaluable subjects per group.

MASTERS-2: Sample size and power were computed by assuming that the true proportions of subjects with various mRS outcomes at the 90-day follow-up visit are consistent with those observed in MASTERS-1 for the population under study in MASTERS-2, making minor adjustments to reflect expectations for MASTERS-2 subjects. Based on this approach, a 1-sided alpha level of 0.025, 300 subjects provide 95% power for testing the study's primary effectiveness hypothesis.

Other alternative outcome estimates were evaluated (a) adjusting the outcome above by reducing the treatment advantage over control, and (b) comparing an adjusted treatment outcome to placebo rates observed in other relevant studies. Several studies were identified with control populations representative of the targeted population for MASTERS-2, taking into consideration stroke severity, concomitant treatments (e.g., tPA), timing of treatment, age, and functional outcomes.

These sensitivity analyses confirm that at 300 subjects (150 subjects per group), the MASTERS-2 study would be adequately powered to test the hypothesis that MultiStem treatment can improve global disability as measured throughout the range of mRS scores by shift analysis.

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 1. Income Statement

Athersys, Inc. Income Statement ($ '000)																	
ATHX: YE Dec. 31	2018A	2019A	2020A	2021A	1Q22A	2Q22E	3Q22E	4Q22E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Product Revenue (000's)																	
MultiStem Ischemic Stroke (U.S.)										-	183,326	367,018	551,077	735,505	920,300	1,105,465	1,290,999
% Chg																	
MultiStem Ischemic Stroke (Japan) - Royalty							-	-	-	-	9,350	21,838	35,131	46,888	58,669	70,473	82,301
% Chg																	
MultiStem Hemorrhagic Stroke (U..S.)					-	-	-	-	-	-	-	59,854	119,828	139,939	160,090	180,282	200,514
% Chg																	
MultiStem ARDS					-	-	-	-	-	-	-	-	-	-	-	-	-
% Chg																	
MultiStem AMI					-	-	-	-	-	-	-	-	-	-	-	-	-
% Chg																	
MultiStem Trauma										-	-	-	-	-	-	-	-
% Chg																	
Total Revenues (Product Sales, Grants & Milestones)	-	-	-	-	-	-	-	-	-	-	192,675	448,710	706,037	922,332	1,139,060	1,356,220	1,573,813
Contract revenues from Healios	22,276	5,517	1,432	5,514	2,912												
% Chg																	
License Fees - Contract revenues	1,461	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
% Chg																	
Grant Revenues	554	116	8	-	-	-	-	-	-	-	-	-	-	-	-	-	-
% Chg																	
Pfizer Milestones																	
% Chg																	
Total Revenues (Product Sales, Grants & Milestones)	24,291	5,633	1,440	5,514	2,912	-	-	-	-	-	192,675	448,710	706,037	922,332	1,139,060	1,356,220	1,573,813
Expenses																	
COGS (excludes royalties)	-	-	-	-	-	-	-	-	-	-	36,665	85,374	134,181	175,089	216,078	257,149	298,302
COGS % Product Sales		20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
R&D	38,656	39,045	62,994	71,080	4,099	8,640	9,000	14,261	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	15,888	20,065	20,944	4,864	5,066	(10,609)	20,266	20,468	20,673	20,880	21,089	21,299	21,512	21,728	21,945
G&A % Rev's																	
Other (depreciation)	855	698	890	1,427	247												
Total expenses	49,953	51,121	79,772	92,572	25,290	13,504	14,066	3,652	56,513	55,388	91,211	139,110	187,140	227,303	267,578	307,964	348,462
Oper. Inc. (Loss)	(25,662)	(45,488)	(78,332)	(87,058)	(22,378)	(13,504)	(14,066)	(3,652)	(53,601)	(55,388)	101,465	309,599	518,897	695,030	871,482	1,048,256	1,225,351
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	53%	69%	73%	75%	77%	77%	78%
Other Income Expense (net)	762	906	(433)	(18)													
Other Income (loss of unconsolidated affiliate				121	162												
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)	(78,765)	(86,955)	(22,216)	(13,504)	(14,066)	(3,652)	(53,439)	(55,388)	101,465	309,599	518,897	695,030	871,482	1,048,256	1,225,351
Taxes	-	-	-	-		(1,891)	(1,969)	(511)	(4,371)	(8,862)	20,293	74,304	145,291	201,559	261,445	324,959	392,112
Tax Rate	0%	0%	0%	0%	14%	14%	14%	14%	14%	16%	20%	24%	28%	29%	30%	31%	32%
Net Income	(24,283)	(44,582)	(78,765)	(86,955)	(22,216)	(11,613)	(12,097)	(3,141)	(49,067)	(46,526)	81,172	235,296	373,606	493,471	610,038	723,296	833,239
Net Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	42%	52%	53%	54%	54%	53%	53%
EPS	(0.18)	(0.29)	(0.42)	(0.39)	(0.09)	(0.05)	(0.03)	(0.01)	(0.17)	(0.10)	0.16	0.45	0.71	0.98	1.29	1.65	2.04
Non GAAP EPS (dil)	(0.16)	(0.27)	(0.40)	(0.37)	(0.09)	(0.04)	(0.02)	(0.00)	(0.16)	(0.09)	0.17	0.46	0.72	0.99	1.30	1.66	2.05
Wgtd Avg Shrs (Bas) - '000s	136,641	151,696	187,472	224,274	244,197	246,639	350,000	351,750	298,146	359,280	370,176	381,402	384,732	369,610	344,395	320,901	299,009
Wgtd Avg Shrs (Dil) - '000s	136,641	151,696	187,472	224,274	244,197	249,081	450,000	459,000	350,569	482,414	507,472	522,862	527,428	506,697	472,130	439,921	409,910

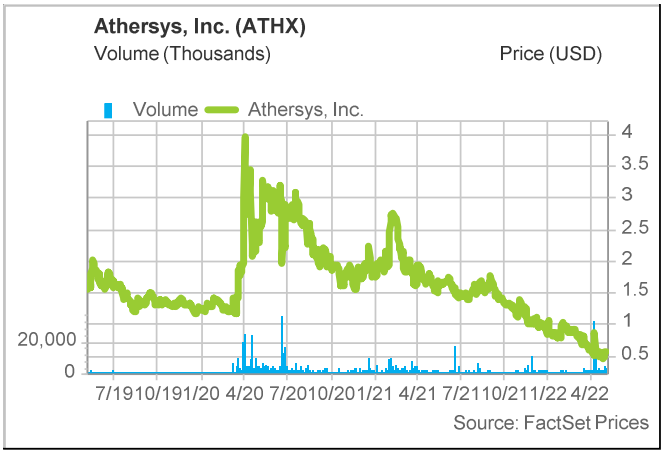
Source: Dawson James estimates, company reports

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
Update – Buy – March 26, 2021 – Price Target $7.00
Update – Buy – March 31, 2021 – Price Target $7.00
Update – Buy – May 7, 2021 – Price Target $7.00
Update – Buy – August 10, 2021 – Price Target $7.00
Update – Buy – November 12, 2021 – Price Target $7.00
Update – Buy – November 16, 2021 – Price Target $7.00
Update – Buy – December 31, 2021 – Price Target $7.00
Update – Buy – March 16, 2022 – Price Target $7.00
Update – Buy – April 4, 2022 – Price Target $7.00
Update – Buy – May 6, 2022 – Price Target $7.00
Update – Buy – May 20, 2022 – Price Target $5.00
Update – Buy – May 31, 2022 – Price Target $5.00
Update – Buy – June 10, 2022 – Price Target $3.00

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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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Current as of 16-May-22

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	31	72%	4	13%
Market Perform (Neutral)	12	28%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	43	100%	4	9%

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